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206-22

Approval report – Proposal P1052

Primary Production and Processing requirements for Horticulture (Berries, Leafy Vegetables and Melons)

Food Standards Australia New Zealand (FSANZ) has assessed a proposal to strengthen food safety in the primary production and processing of fresh berries, leafy vegetables and melons sectors and prepared three standards (one for each commodity) and a consequential variation to the Code. These measures apply to Australia only and are to be supported by non-regulatory measures to improve food safety knowledge, risk management and culture.

On 17 November 2021, FSANZ sought submissions on the three draft standards and the consequential variation, and published an associated report. FSANZ received 32 submissions.

After having regard to the submissions received and the relevant matters as set out in this report, FSANZ approved the draft standards and consequential variation on 8 June 2022. The Australia and New Zealand Ministerial Forum on Food Regulation was notified of FSANZ's decision on 22 June 2022.

This Report is provided pursuant to paragraph 63(1)(b) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

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Supporting documents

The following documents which informed the assessment of this Proposal are available on the [FSANZ website](#):

- SD1 Decision Regulatory Impact Statement
- SD2 Cost–Benefit Analysis

Executive summary

The majority of horticultural produce in Australia is safely produced and is an important part of a healthy and balanced diet. However, foodborne illness outbreaks, deaths, product recalls and other food safety incidents in Australia linked to horticulture, continue to occur. In June 2018, the then Australia and New Zealand Ministerial Forum on Food Regulation (now the Food Ministers' Meeting) noted the increase of outbreaks and requested that Food Standards Australia New Zealand (FSANZ) reassess food safety risk management across several horticultural sectors.

This FSANZ proposal reviewed food safety in primary production and processing of fresh berries, leafy vegetables and melons. FSANZ has assessed the proposal in accordance with the *Food Standards Australia New Zealand Act 1991* (Cth). Our assessment included an analysis of the current regulatory and non-regulatory environment in Australia and overseas, a microbiological assessment, cost-benefit analysis (CBA), two public calls for submissions and a survey of primary producers and processors.

The microbiological assessment identified hazards of concern, contamination sources and risk mitigation control measures for primary production and processing of berries, leafy vegetables and melons. The microbial hazards of greatest concern are:

- for berries: shiga toxin-producing *Escherichia coli* (STEC), norovirus (NoV) and hepatitis A virus (HAV)
- for leafy vegetables: STEC, non-typhoidal *Salmonella* spp. (*Salmonella*) and *Listeria monocytogenes* (*Listeria*)
- for melons: *Salmonella* and *Listeria*.

The most likely sources of produce contamination include animals, growing location, extreme weather events, soil, manure and composts, water inputs, postharvest washing and sanitisation, and poor worker and equipment hygiene.

Our analysis identified that there are no nationally consistent regulatory requirements for food safety that apply to the primary production and processing of horticultural produce, except for seed sprouts. There is instead a reliance on industry self-regulation, such as through food safety schemes (FSS). FSANZ's assessment is that FSS are important, however uptake is incomplete and inconsistent. This issue creates an uneven playing field and inadequate coverage to effectively address food safety risks across the three sectors.

The CBA attributed the current annual cost of illness of microbiological hazards as: \$4.4 million for berries, \$9.3 million for leafy vegetables and \$7.1 million for melons.

FSANZ considered the extent of foodborne illness attributed to the three sectors, cost to industry and government of introducing food safety measures, and protection of consumer health and safety. We assessed four options:

- option 1 – Retaining the status quo
- option 2 – Introducing regulatory measures
- option 3 – Introducing a combination of regulatory and non-regulatory measures
- option 4 – Introducing non-regulatory measures alone.

Option 3 is FSANZ's preferred option. A combination of regulatory and non-regulatory measures presents the most cost-effective and appropriate way to protect the health of consumers and reduce foodborne illness from these horticulture sectors.

The regulatory measures are three new primary production and processing standards in the Australia New Zealand Food Standards Code: one each for berries, leafy vegetables and

melons, and a consequential variation to the Code. These standards provide nationally consistent, outcomes-based requirements for primary producers and primary processors of the three commodities. The requirements directly address key food safety risks, including causal factors of foodborne illness linked to these sectors. Requirements were developed considering identified risks, costs and benefits, and stakeholder views and submissions. The standards represent the minimal regulation needed to achieve safe produce in each sector, and achieve a net benefit for each commodity group. As requirements align closely with existing industry FSS, impacts on businesses already operating under a FSS are reduced.

Two rounds of [public consultation were undertaken to support this work](#). The first call for submissions was held in February 2020 and the second was held in November 2021. Each submission received was considered as part of our assessment.

Most stakeholders indicated full or conditional support for the proposed approach. There is strong consensus on the need for national measures to establish a base level of food safety risk mitigation and create an even playing field for businesses. Industry support for regulation is conditional on recognition of existing FSS as meeting proposed regulatory requirements.

The draft standards provided in the second call for submissions were amended after further consideration and new evidence, including submissions received. FSANZ approved the amended draft standards and a consequential variation to the Code, which are at Attachment A. The related explanatory statements are at Attachment B.

A 30-month implementation period will be in effect from the date of gazettal for all three standards and the consequential variation. Implementation of the standards is the responsibility of state and territory food regulators. To support implementation, jurisdictions have committed to exploring recognition of existing FSS as meeting proposed regulatory requirements. FSANZ will work with jurisdictions to support businesses not on a FSS to ensure food safety obligations are understood and met across the three sectors. This includes targeted support for smaller businesses.

Development of non-regulatory measures is strongly supported by governments and industry to help facilitate understanding, uptake and implementation of the standards. FSANZ is working with food regulators and industry to develop nationally consistent resources on the new requirements and best practice. These resources may be provided in a variety of languages, formats and delivery modes to reach the diversity of businesses in these sectors.

Introduction

1.1 The Proposal

This proposal was prepared to review food safety risks in specific horticulture sectors—fresh berries, leafy vegetables and melons—and determine whether amendments to the Australia New Zealand Food Standards Code (the Code) are required to manage these risks.

Ministers responsible for food regulation requested this review in response to several significant foodborne illness outbreaks involving fresh produce. These outbreaks indicate a potential failure to prevent food safety problems during primary production and processing, particularly where complex supply chains impact food safety and traceability. Ministers requested FSANZ consider all available options, including the need for standards development, to determine if there could be potential net benefits from well-targeted interventions.

For this assessment, FSANZ analysed:

- public health and safety risks
- economic and social factors
- existing requirements (e.g. state and territory legislation and internationally)
- industry codes of practice and guidelines
- accredited food safety systems.

The Implementation Subcommittee on Food Regulation (ISFR) established the Horticulture Implementation Working Group (HIWG) to work with FSANZ during the proposal, to ensure a consistent approach to any Code amendments. This group includes regulators from each state and territory and the Australian Government Department of Agriculture, Water and the Environment (DAWE).

FSANZ established a Standard Development Advisory Group (SDAG) to provide advice during the assessment. The SDAG includes representatives of key peak industry bodies and government food regulators from each state and territory.

1.2 The current situation

In Australia, a through-chain regulatory approach to managing food safety (i.e. from production on the farm through to sale to consumers) is provided through two main chapters of the Code. Chapter 4 contains standards for primary production and processing (PPP) and Chapter 3 contains food safety standards for all other food businesses.

There are no national regulatory requirements for horticulture primary production and processing, except for seed sprouts (Standard 4.2.6). To address this gap, some jurisdictions have amended their food acts and relevant regulations to apply food safety requirements to some horticulture primary production and/or processing businesses. However, the measures are not present in every jurisdiction and where they do exist, are not consistent across jurisdictions. Regulation for exported horticultural products focuses primarily on biosecurity.

The current regulatory situation results in limited access for regulators to growing and processing sites; occurring mostly in response to a food safety emergency. In addition, regulators have limited knowledge on where and how businesses in these sectors are operating, impeding a rapid response if a food safety issue arises. There is no provision for them to proactively monitor and strengthen food safety management on farm.

Non-regulatory measures include industry food safety schemes (FSS), retailer requirements,

codes of practice and other guidance. FSANZ considers these measures are important food safety measures for horticulture as better food safety outcomes occur when there is business buy-in. However, uptake is incomplete and inconsistent, meaning food safety management is not as strong as it could be. Unless businesses are supplying major retailers, there is a lack of incentive for some businesses to operate under a FSS.

1.3 Reasons for preparing the proposal

FSANZ developed this proposal to consider whether the introduction of nationally consistent, minimum standards is required to address food safety risks with these three commodities.

FSANZ's primary objective is protecting public health and safety. While the vast majority of fresh produce is safe and healthy, foodborne illness linked to particular horticultural commodities continues to occur. In Australia and internationally, foodborne illness, deaths, product recalls and other food safety incidents continue to be associated with fresh horticultural produce. The impacts of these events are felt by:

- consumers (illness and potential death, particularly in the elderly)
- businesses (both affected and implicated businesses in the same sector)
- horticultural sectors (an entire sector may feel the effects of a localised outbreak)
- governments (costs of responding and investigating causes)
- domestic markets
- export markets.

Such events present a significant cost to the Australian economy, yet are largely preventable through appropriate food safety measures.

During 2011–2019 there were ten outbreaks of foodborne illness associated with the consumption of horticultural produce in Australia. Berries, leafy vegetables and melons were associated with seven of the ten outbreaks, as follows:

- two outbreaks were linked to HAV in imported berries—no outbreaks were linked to domestically-produced product
- three outbreaks were linked to *Salmonella* Anatum and NoV in domestically produced leafy vegetables
- two outbreaks, resulting in 275 reported cases and 10 deaths, were linked to *Salmonella* Hvitittingfoss and *Listeria monocytogenes* in domestically-produced melons.

1.4 Procedure for assessment

The Proposal was assessed under the Major Procedure of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

1.5 Decision

FSANZ's decision is that a combination of regulatory measures and non-regulatory measures is needed to effectively manage food safety risks in the three sectors. This is option 3 of the four options assessed. The regulatory measures are three new primary production and processing standards (one each for berries, leafy vegetables and melons) and a consequential variation to the Code. These measures were proposed in the 2nd call for submissions (CFS). FSANZ assessed stakeholder submissions and data, and amended the three draft standards following feedback. These amendments improve clarity, strengthen some food safety requirements and provide extra time for implementation of the standards. FSANZ decided to approve the three draft amended standards and the consequential variation, all which will take effect 30 months after gazettal.

The approved draft amended standards and the approved consequential variation are at Attachment A. The related explanatory statements are at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

Non-regulatory measures continue to be developed through a process largely coordinated by state jurisdictions and in consultation with industry. These will include fact sheets, posters, web pages, webinars, and videos explaining the requirements and demonstrating best practice.

2 Summary of findings

2.1 Issues raised by stakeholders

FSANZ held two rounds of public consultation and a series of targeted stakeholder consultations, including farm visits, meetings and a survey of growers and processors (see section 2.4). The relevant documents and submissions received for both calls for submissions are published on the FSANZ website at [P1052 – PPP Requirements for Horticulture \(Berries, Leafy Vegetables and Melons\)](#).

At the 1st public CFS we sought feedback on our initial statutory assessment, including proposal scope, assessments of the current regulatory and non-regulatory environment, Australian production of melons, berries and leafy vegetables, and foodborne illness outbreaks and recalls linked to these sectors. Our preferred position at that time was for regulation in some form, to strengthen food safety management.

We received 27 submissions in response to the 1st CFS. Government submissions supported regulation, stating current measures were inadequate to manage known food safety risks. In general, industry supported the status quo and expressed concerns that regulation wouldn't recognise industry efforts to address food safety and may cause additional burden. Also there was concern that the proposal focuses only on three commodities. Further details of issues raised by stakeholders in response to the first CFS are provided in our [2nd CFS report](#).

Submissions received informed our decision on whether to prepare draft regulatory measures. Prior to the 2nd CFS, we assessed four risk management options (see section 2.3.1). We refined our initial assessment based on information provided in submissions, newly available data and a revised cost-benefit analysis. The 2nd CFS report, and accompanying Consultation Regulation Impact Statement (CRIS), presented our findings and our revised preference for a combination of regulatory and non-regulatory measures (option 3). Three draft primary production and processing standards to manage key food safety risks in the three commodities, and a consequential variation to the Code were prepared and provided for comment. Stakeholders were also invited to provide data and other information on the costings and assumptions we made in our assessments.

In response to the 2nd CFS, 32 submissions from government, industry associations, businesses and individuals were received. Table 1 summarises the submissions and FSANZ's responses. Overall, most submitters supported option 3, affirming the need for national minimal standards to address food safety risks for the three commodities. While government strongly supported the proposed regulatory measures, industry support for this option was largely conditional on recognising food safety schemes (FSS) as meeting any new requirements. Representatives of the melon industry, NT Farmers and small businesses were not supportive of regulation.

Implementation of the proposed standards was a major theme. Industry stakeholders voiced

concern regarding inconsistencies across jurisdictions, and additional costs and administration, particularly if existing FSS are not recognised. Most regulators (in submissions and through the HIWG) committed to exploring recognition of Global Food Safety Initiative (GFSI)-benchmarked FSS as a way of demonstrating compliance with the standards, including use of through-chain data monitoring. Further detail on implementation were provided by industry and government.

There was strong agreement on the need for non-regulatory measures, particularly guidance and education about food safety in horticulture and supporting materials. These measures will help businesses better understand food safety risks and controls in horticultural production settings, as well as their obligations to produce safe food. Best practice resources and education are seen to provide a much-needed link between requirements of the standards and improvements in food safety culture. Many submissions focussed on the need to support small businesses. Small businesses and those not already on a FSS were considered priorities for future outreach.

Submissions raised the scope of the standards, with preference for minimum level food safety requirements that apply to all horticulture produce rather than single commodities. Amendments to some specific requirements were sought (e.g. definitions, traceability and soil inputs). Stakeholders also requested an extension to the transition period, to allow for jurisdictional legislative changes, and development of processes, resources, and skills and knowledge.

Table 1: Summary of issues

The main points raised in submissions and FSANZ's responses to issues are summarised below. Note column 3 indicates the broad stakeholder group which raised the point and there may be some within that stakeholder group with a divergent view. Each submission is published and can be read separately to this summary.

	Issue/ Theme	Stakeholder groups	FSANZ response
	Support for option 3/ regulation		
1	<ul style="list-style-type: none"> Option 3 presents a cost-effective approach to reducing foodborne illness that is evidence- and risk-based. It provides for a nationally consistent, through-chain approach, sets a level playing field, sets similar requirements to industry food safety schemes (FSS), allowing for recognition of industry tools, and aligns internationally. Standards should be supported by non-regulatory measures Sets the base level food safety requirements for all producers of berries, leafy vegetables and melons Will support pro-active engagement and better relationships with/understanding of businesses Will enhance consumer confidence and support Australia's trade reputation Will provide a mechanism for jurisdictions to use their legislation to check businesses are implementing the standards Recognises needs of small businesses through non-regulatory support and a range of compliance tools and options Industry will/may benefit in regaining and maintaining market share if an incident or recall occurs Other potential benefits - fewer food safety related incidents (leading to withdrawal and recalls), improved product quality and extended shelf-life of product due to greater control 	Government; Industry association; Business	<p>Agree.</p> <p>For the reasons summarised in this report and its supporting documents, FSANZ's assessment is that the approved draft standards ('the standards') will provide nationally consistent through-chain food safety measures that will reduce the incidence of foodborne illness attributed to melons, leafy vegetables and berries.</p> <p>By establishing minimum food safety requirements in the Code, the standards set the expectations for all producers and accompany them with guidance to support consistent uptake. This work contributes to achieving Australia's Foodborne Illness reduction Strategy 2018-2021+. The standards are considered in the context of the benefits to the community of reducing foodborne illness and the costs associated with illness. See SD1 and SD2 for further details.</p>
2	<ul style="list-style-type: none"> Conditional support for option 3, if there is recognition of FSS that are Global Food Safety Initiative (GFSI) benchmarked; GFSI-FSS should be recognised as demonstrating compliance 	Industry association; Business	<p>Conditional support is noted. For the reasons summarised in this report, FSANZ considers recognition of FSS is an important but secondary step to establishing minimum food safety requirements.</p> <p>FSANZ acknowledges industry commitment to food safety principles</p>

			and existing industry-developed tools such as Freshcare and other FSS and supporting materials such as the Melons Toolbox. FSANZ notes this is an implementation matter which has been considered during standards development with the Standards Development Advisory Group (SDAG). Discussions are ongoing with jurisdictions on a model to recognise GFSI-FSS as part of a broader scheme of compliance tools, supporting nationally consistent implementation.
Other comments on regulation			
3	<ul style="list-style-type: none"> Standards would also be useful in New Zealand to reduce illness attributed to these commodities 	Industry association	Noted, however this is outside the scope of the proposal for Australian horticulture. The standards do not apply in New Zealand. The Agreement between the Government of Australia and the Government of New Zealand establishing a System for the Development of Joint Food Standards excludes standards relating to 'the specification of food hygiene provisions including requirements for food safety programs or other means of demonstrating the safety and compliance of foods'.
4	<ul style="list-style-type: none"> Regulation should be risk- and size-based considering tonnage of product 	Industry association	The standards are risk based in that the measures are proportionate to the risks that need to be managed to reduce the incidence of foodborne illness. The standards are outcome based and provide for the flexible implementation of specific food safety measures that are commensurate with the business's activities. This approach is consistent with the Overarching Policy Guideline on Primary Production and Processing Standards. See SD1 and SD2 for more information.
5	<ul style="list-style-type: none"> A single standard, not 3 different ones, is better for a nationally consistent approach 	Industry association	Noted. However, for the reasons stated in this report, FSANZ approved a separate standard for each commodity. Each contain customised risk management measures for the specific commodity where unique hazards may occur for that commodity. Some requirements will be similar across the standards and the commodities as there are similar hazards to be managed along the production chain.
6	<ul style="list-style-type: none"> Regulation should focus attention on those not on a FSS 	Industry association; Business	FSANZ's position is that minimum food safety requirements should be established for all producers. This is because hazards exist that need risk mitigation, regardless of whether or not a business is on a FSS. As explained in this report, FSANZ's assessment, based on the best available evidence, is that approval of national food regulatory

			standards that mandate compliance with specific food safety requirements, supported by non-regulatory measures, provides greatest benefit. Food safety performance (i.e. whether individual requirements are being met), as well as considering businesses not on a FSS are also matters that can be considered and accounted for in implementation. FSANZ understands that jurisdictions are discussing implementation models with industry as part of a broader scheme of compliance tools, that would recognise FSS so resources can be focussed on those not on a FSS.
7	<ul style="list-style-type: none"> Support some regulation, but not the full standards as proposed – considering work load of local councils 	Government	FSANZ's assessment based on the best available evidence is that approval of the full draft standards was and is warranted. The purpose of these measures is to reduce the burden of foodborne illness for the community by establishing minimum food safety requirements. While there may be some additional workload with implementing the measures, this workload will be outweighed by the benefits to the community. See in particular SD1 and SD2.
Opposed to regulation / option 3			
8	<ul style="list-style-type: none"> The regulatory approach provides no commercial incentives, no increase in food safety above current schemes, no access to export or domestic markets, will not enable an increased produce sale price, and is unlikely to assist/protect business categories after a food safety incident 	Industry	Noted. FSANZ's evidence-based assessment is that the regulatory approach and approval of the draft standards is warranted. See SD1 and SD2. The standards for berries, melons and leafy vegetables provide for through-chain food safety measures to reduce foodborne illness attributed to these commodities. The national-level legal foundation of standards will provide for greater confidence for consumers and customers (both domestic and international) in the safety of these products. These enhancements in domestic food safety regulation support Australia's reputation as a supplier of safe food to export markets, benefitting the industry in regaining and maintaining market share in the event of an incident or future recall. Regulator awareness of businesses and traceability requirements will enable faster response to food safety incidents if they occur.
9	<ul style="list-style-type: none"> Standards will likely cause duplication of processes, increased costs and administration, confusion from inconsistent implementation; could push small businesses out 	Industry association; Government	The standards address risks and provide for nationally consistent through-chain food safety measures to reduce the incidence of foodborne illness attributed to melons, leafy vegetables and berries. Implementation was considered in developing these measures. FSANZ notes that jurisdictions have and are actively engaged with industry on how best to implement the measures.

10	<ul style="list-style-type: none"> FSANZ's assumed effectiveness of regulation is unproven – self regulation is proven in the horticulture sector 	Industry association	FSANZ disagrees. FSANZ's assessment is that self-regulation has resulted in an incomplete and inconsistent uptake of industry-based FSS and no proven reduction in foodborne illness, creating an uneven playing field and costs for measures that may be insufficient to address relevant food safety risks. The standards provide a nationally consistent through-chain approach that is focussed on managing the relevant risks. See SD1 and SD2.
11	<ul style="list-style-type: none"> Standards are unlikely to solve ongoing issues after produce leaves the farm gate – need attention further down chain, including at retail and for further processed product 	Industry association; Government	The standards focus only on primary production and processing stages. Risks that may occur further along the supply chain are addressed under existing food safety measures under Chapter 3 of the Code. For instance, further processed horticulture such as cut melons are subject to food safety requirements under Chapter 3 including temperature control and protection from contamination. Standards are developed to avoid duplicating requirements already covered. Chapter 3 requirements already apply to horticulture products sold at retail, direct to consumers or that have been further processed.
12	<ul style="list-style-type: none"> Small scale farmers should be less impacted, especially those selling direct to consumers/restaurants as they present lower risk from lengthy supply chains or large numbers of consumers 	Industry association	For the reasons stated in this report, FSANZ's assessment is that approval of the standards is warranted. Each standard is risk based in that the measures are proportionate to the identified risks that must be managed to reduce the incidence and impact of foodborne illness. The standards are outcome based and provide for the flexible implementation of specific food safety measures that are commensurate with the business's activities. See also SD1 and SD2.
13	<ul style="list-style-type: none"> Further industry consultation is needed during standard development stage to clarify full impacts of implementation 	Industry association	Noted. Jurisdictions are responsible for implementation. Jurisdictions have committed to further consultation with industry in developing implementation models, including exploring recognition of existing FSS as meeting the requirements introduced by the standards. FSANZ worked closely with all stakeholders throughout the assessment process, including the cross-government working group (HIWG) and industry/government working group (SDAG). Due consideration was given to matters such as costs and benefits, implementation and fair playing field. See also SD1 and SD2.
14	<ul style="list-style-type: none"> Regulation would prohibit young people returning to small-scale farms and inhibit communities' access to fresh local food. UN Declaration asserts States shall facilitate direct farmer-to-consumer sales 	Industry association	This work is focused on the protection of public health and addressing identified food safety risks. The standards have been developed to be the minimum required to address those risks and to protect public health. Food safety requirements already exist in Chapter 3 that cover direct farmer-to-consumer sale.

15	<ul style="list-style-type: none"> • Potential crossover and conflict with other legislation, and a potential burden for local governments 	Government	FSANZ's assessment based on the best available evidence is that approval of the full standards was and is warranted. The purpose of these measures is to reduce the burden of foodborne illness for the community by establishing minimum food safety requirements. While there may be some additional workload with implementing the measures, this workload will be outweighed by the benefits to the community. See SD1 and SD2.
16	<ul style="list-style-type: none"> • Non-regulatory measures should suffice or be the focus of additional effort: education, auditing and random checks on FSS – should not assume maximum FSS coverage has been reached 	Industry association	As explained in this report, FSANZ's assessment is that regulatory measures are required, to ensure nationally consistent food safety measures are implemented. Non-regulatory measures cannot compel compliance, but they can support the regulatory measures as part of an implementation strategy.
Scope of proposal			
17	<ul style="list-style-type: none"> • Support for PPP scope to be broadened to include other commodities - <ul style="list-style-type: none"> ○ Expand to other commodities associated with foodborne illness including dates, semi-dried fruit, nuts, fresh herbs and fresh coconut ○ Further address request from Ministers (June 2018) particularly sprouts ○ All of horticulture (see below) 	Government	<p>The initial request from the Forum in 2018 was for FSANZ to assess food safety risk management of five high-risk horticulture sectors: ready-to-eat, minimally processed fruits and vegetables, fresh leafy green vegetables, melons, berries and sprouts.</p> <p>The scope of P1052 focussed on berries, leafy vegetables and melons after consideration that regulatory measures already existed for seed sprouts (Standard 4.2.6), and ready-to-eat minimally processed fruits and vegetables (Chapter 3). P1052's focus on the three commodities is consistent with Codex guidance, which highlights food safety risks associated with berries, leafy vegetables and melons in specific annexes of the Code of Hygiene Practice for Fresh Fruit and Vegetables.</p> <p>FSANZ may consider other commodities further as a part of the broader review of Chapter 4 of the Code.</p>
18	<ul style="list-style-type: none"> • Support for scope to be broadened to include all horticulture – <ul style="list-style-type: none"> ○ noting risks and other issues identified by FSANZ (uptake of FSS, uneven playing field, regulator challenges identifying businesses, consumer awareness of production processes) apply across the sector ○ noting international legislation across whole sector, potentially leaving Australia at a disadvantage for mutual recognition 	Government; Industry association; Business	See response above at issue 17.

	<ul style="list-style-type: none"> ○ consider at least minimal requirements similar to berries; or notification for all businesses / and minimal traceability requirement ○ focus on processes (ie risks) rather than commodities ○ prioritise for future work under Chapter 4 review if not addressed in this proposal ○ some growers may shift to other 'non-regulated' commodities 		
19	Berry standard - Supported: Absence of illness linked to domestic berries does not equate to absence of food safety risk; standards will improve traceability, focus industry on key risks	Government	The microbiological assessment identified hazards in domestic berry production. The standard recognises these hazards and establishes minimum requirements to manage them. Standards are developed to manage potential food safety risks i.e. where hazards can occur with a commodity at different stages of production.
20	Berry standard - Not supported: No evidence of foodborne outbreaks attributed to domestic berries. Outbreaks linked to imported berries, where risks are different (e.g. endemic Hepatitis A virus, proximity to animals). Risks identified also apply to many other fresh commodities	Industry association; Business	See response above at issue 17 and 19.
Industry food safety schemes (FSS)			
21	<ul style="list-style-type: none"> ● Existing FSS, especially GFSI-benchmarked, should/must be recognised as meeting requirements – or recognised via notification/certificate lodgement, and the FSS be identified in standard/compliance plans 	Industry association; Business	The standards adopt an outcomes-based approach to enable a degree of flexibility in how businesses comply. Existing FSS can be compared with the requirements and, where appropriate, may be recognised by jurisdictions under a recognition model. The standards do not refer to particular FSS, as that would be unnecessarily prescriptive, require listing of schemes and would not be consistent with an outcomes-based approach.
22	<ul style="list-style-type: none"> ● Industry should be given choice of regulation or self-regulation (through FSS) 		As explained in this report, FSANZ's assessment is that regulation in combination with non-regulatory measures is the better regulatory option. See SD1 and SD2. Self-regulation has resulted in incomplete and inconsistent uptake of FSS, creating an uneven playing field and costs for measures that may be insufficient to address relevant food safety risks. The standards provide a nationally consistent through-chain approach that is focussed on managing the identified risks.
23	<ul style="list-style-type: none"> ● Industry and regulators should work together to use existing FSS rather than introducing regulation – especially to bring smaller businesses under FSS or equivalent and to streamline admin eg for notification 	Industry association; Business	See responses 21 and 22. The risk assessment identified hazards occur in production of the three commodities and the standards establish minimum requirements to manage them and to protect public health and safety. Further consultation is ongoing with jurisdictions responsible for implementing the standards, to explore a recognition model as part of a broader scheme of compliance tools.

24	<ul style="list-style-type: none"> HARPS standard is more rigorous for food safety than GFSI-FSS, covers retail and closely aligns to proposed standards at the farm level 	Industry association	The standards deal with managing the risks, rather than prescriptively specifying 'how' those risks can be managed. The measures adopt an outcomes-based national approach across all businesses, with which FSS can be compared. Primary production and processing standards do not cover further processing or retail sale – these are covered under Chapter 3.
25	<ul style="list-style-type: none"> FSS are in effect mandatory for businesses, for retail supply approval 	Industry association; Business	FSANZ agrees that many businesses can demonstrate a strong commitment to food safety through their FSS. FSANZ notes industry commitment to food safety is essential for good food safety outcomes. However, as explained in this report, FSANZ's assessment is that FSS uptake is incomplete and inconsistent, creating an uneven playing field and costs for measures that may be insufficient or inadequately implemented to address relevant food safety risks. See SD1 and SD2. The standards adopt an outcomes-based national approach across all businesses, with which FSS can be compared.
26	<ul style="list-style-type: none"> Government acknowledge some businesses are on FSS, but participation is voluntary, FSS are not taken up / not accessible to all and FBI has still occurred Jurisdictions are committed to exploring recognition of GFSI-benchmarked schemes as a means of demonstrating compliance with standards' requirements 	Government; Industry association	FSANZ agrees industry scheme uptake is incomplete and inconsistent, which can lead to risks not being managed. FSANZ notes jurisdictions' commitment to exploring recognition of GFSI-benchmarked FSS as part of a broader scheme of compliance tools.
Consultation package/process			
27	<ul style="list-style-type: none"> Standard development process should have consulted further with industry to understand full impacts of implementation, not enough industry input 	Industry association	As explained in this report and in the preceding two CFS, FSANZ's consultation to date has been extensive. All submissions received during each round of consultation were considered. FSANZ's assessment had regard to the impact of regulation on industry as shown by, for example, SD1 and SD2. FSANZ notes jurisdictions' stated commitment to work cooperatively with industry in implementation.
28	<ul style="list-style-type: none"> FSANZ assessment does not consider (melon) industry's significant investment into best practice and tools since 2018 outbreak 	Industry association; Business	Incorrect. Standards are developed to manage potential food safety risks. FSANZ took account of the substantial investment and introduction of a range of measures by the melon industry, including collaborative efforts with NSW Department of Primary Industries. The standards are outcomes-based enabling a degree of flexibility in how businesses comply. Jurisdictions can, where appropriate, recognise FSS for compliance purposes. FSANZ notes current discussions between jurisdictions and industry on developing a regulatory

			recognition model for implementation as part of a broader scheme of compliance tools. The 30-month transitional period provides the time to develop that model to minimise costs and duplication.
29	<ul style="list-style-type: none"> Skewed perspective focussing on % of businesses on FSS - should look at production volume 	Industry association	See response to issues 4 and 12.
30	<ul style="list-style-type: none"> Some comments on costing estimates – limited additional data provided 	Industry association	FSANZ's assessment was based on and had regard to the best available evidence. FSANZ has considered all submitted data and costing estimates in finalising our approach. Updated and more sophisticated modelling on costs of illness are provided in SD1.
Suggested changes to requirements			
All 3 standards			
31	<ul style="list-style-type: none"> Suggest fewer requirements, just covering skills and knowledge and requirement to be on a FSS, with (preferably external) review of FSS linked to notification to government 	Government	FSANZ disagrees. As explained in this report, FSANZ's assessment is that each requirement contained in the standards is warranted. Through-chain food safety measures are needed to ensure all the relevant risks are adequately managed. The focus of the standards is to manage identified risks critical to food safety.
32	<ul style="list-style-type: none"> Application section should include clause (similar to seafood standard), to clarify the standard does not apply to the retail sale activities or manufacturing (currently this information is only in explanatory statement) 	Government	Each standard already explicitly states (in section 3 - Application) that the standard does not apply to retail sale. FSANZ has reconsidered the issue of referencing manufacturing, in response to feedback from consultation, and amended all three standards to explicitly exclude manufacturing (in section 3 - Application).
33	<ul style="list-style-type: none"> Animal management: All standards should be revised to provide guidance on safe management and withholding periods when animals are integrated into farming systems, rather than prohibiting inclusion of animals in production systems 	Industry association	FSANZ's assessment is that this would be an unnecessarily prescriptive and impractical approach to managing animals on premises where the relevant commodities are produced or processed. The standards do not prohibit the presence of animals but they do require the risks associated with animals to be managed so that they do not render the produce unacceptable. This outcomes-based approach ensures that unnecessarily restrictive measures are avoided while still ensuring food safety risks are adequately managed.
34	<ul style="list-style-type: none"> Remove 'chopping' from primary processor activities to remove confusion with Chapter 3 activities 	Government	Agreed. FSANZ has reconsidered the drafted primary processor activities, and removed 'chopping' from the definitions of <i>primary horticulture processor</i> and <i>relevant activities</i> .
35	<ul style="list-style-type: none"> The term 'unacceptable' should be clarified, or preferably just focus on food safety in the standards 	Industry association	The term is already defined in Standard 4.1.1–clause 3 and applies for the standards. The use of the term in the standards is consistent

			with its use in the seed sprouts primary production and processing standard (Standard 4.2.6).
36	<ul style="list-style-type: none"> Traceability requirement could include timeliness and standardisation of terminology and documentation 	Government	The standards for traceability align with the approach used in the seed sprouts Standard 4.2.6. At this time, FSANZ considers this approach is sufficient and this comment would add prescription.
37	<ul style="list-style-type: none"> Explicitly state requirement to notify/register (melon and leafy vegetable standard)— or amend 4.1.1 	Government	An express requirement to notify is not required in this case. The two standards (4.2.8 and 4.2.9) will require compliance with the general food safety management requirements. Standard 4.1.1 sets out these management statement requirements, including the requirement that the relevant statement be approved or recognised by the regulatory authority. This in effect requires the business to notify their regulatory agency of their existence as well as their operations.
38	<ul style="list-style-type: none"> Chemicals waste management – recommend including requirement (standard/compliance plan) that waste material and containers be controlled in a way that does not pose a risk of contamination 	Government	Management of containers and waste material on the premises is captured by the premises requirement to be clean to ensure that produce is not made unacceptable.
39	<ul style="list-style-type: none"> Compliance plans insufficient guidance, needs considerable attention. Additional comments provided on compliance plans 	Government; Business	Draft compliance plans and guidance were developed by the HIWG and published with the 2 nd CFS to provide examples of what each standard—if endorsed by the Food Ministers Meeting—would look like at a practical level and to seek stakeholder feedback. FSANZ will provide comments and questions received to the HIWG for further discussion among the jurisdictions. As explained above, jurisdiction-industry discussions to support understanding and implementation are ongoing and are expected to continue through the proposed implementation period if the standards are gazetted following consideration by the Food Ministers Meeting.
Berry standard			
40	<ul style="list-style-type: none"> Definitions: need to clarify e.g. referring to ‘<i>rubus</i>’ or Schedule 22 or specific list or botanical characteristics 	Government; Industry association; Business	Agreed. FSANZ has amended the definition of berries to include berries of the genus <i>Rubus</i> , to help clarify the berries to which the standard applies. The definition draws on the common meaning of berries, while including specific berries within the scope of the standard. This is the most practical means of specifying the berries within the standard and reflects the approach the Forum Ministers used in their request to FSANZ, as well as Australia’s Foodborne Illness reduction Strategy 2018-2021+. FSANZ did not adopt Schedule 22 of the Code to be applicable in this case. The classification of foods by that Schedule and adopted in related standards was not developed by reference to microbiological

			hazard or for the purpose of managing such hazards. The approach FSANZ has taken is consistent with Codex guidance hygienic production of fresh fruit and vegetables.
41	<ul style="list-style-type: none"> Should list refrigerated storage or modified atmosphere storage as part of the listed activities for primary horticulture processors 	Industry association; Business	Agreed. FSANZ agrees storage of harvested produce is an activity associated with primary production and processing and has amended the definitions of <i>primary horticulture processor</i> and <i>relevant activities</i> to include storage.
42	<ul style="list-style-type: none"> Berry traceability clause should include identification of berry growing site, not just 'from whom berries were received' as it might be the same producer but a different site. Suggest 'The growing site of the berries or from whom berries were received...' 	Industry association; Business	Agreed. FSANZ has sought additional information on berry supply chains and amended the traceability clause in the berry standard to include identification of the growing site. This detail will assist with product traceability if a food safety issue occurs or a food recall is required.
43	<ul style="list-style-type: none"> Extent of sanitisation in Premises clause is unclear. Suggest 'maintained, cleaned and if necessary sanitised to the extent required...' 	Industry association; Business	FSANZ considers no change in the wording of the requirement is necessary. However, further clarification has been provided in the standards' explanatory statement.
44	<ul style="list-style-type: none"> Notification requirement should include identification of business's FSS. Extra records for businesses not on FSS (e.g. water and fertiliser inputs, harvest records) could be included 	Industry association; Business	See responses 21-23. FSANZ considers this is an implementation matter. The standards adopt an outcomes-based national approach across all businesses, with which FSS can be compared.
45	<ul style="list-style-type: none"> Should include extra requirements for general food safety management statement, managing produce post weather events, growing site, animals and pests — these are basic GAP and in existing FSS. Strawberry risks not adequately addressed 	Government; Business	FSANZ reconsidered the inputs requirements for berries and included extra requirements for soil, soils amendments and fertilisers to address risks with berries grown in close proximity to the ground (e.g. strawberries). FSANZ's assessment based on the best available evidence is that the standard for berries, as amended, is commensurate with the identified risks and adequate to manage those risks. Comments on and information about implementation have been passed to HIWG for further discussions among the jurisdictions.
46	<p>Soil clause:</p> <ul style="list-style-type: none"> Agree inclusion of soil and fertiliser and mulch input requirements is appropriate especially for berries with close proximity to ground. Is in FSS, will help raise awareness, and help regulators if there is a food safety issue 	Government; Industry association; Business	See response 45. The inputs clause has been amended to include requirements for soil, soils amendments and fertilisers.
47	<ul style="list-style-type: none"> Re-consider requirement to monitor the temperature of harvested Berries – as per Codex Annex for Berries 	Business	As explained above, FSANZ's assessment is that requirements of the berry standard are commensurate with the identified risks.
Leafy vegetable standard			
48	<ul style="list-style-type: none"> Definition: need to clarify e.g. referring to Schedule 22, specific list or botanical characteristics. Unclear whether produce such as 	Government; Business	Agree. FSANZ has reconsidered the <i>leafy vegetables</i> definition based on consultation feedback and amended it for improved clarity.

	Asian leafy veg, spring onions/shallots, leeks, potatoes, radishes, etc. would be included		The intent is that the standard applies to any vegetable with one or more leaves when the leaves may be consumed fresh (raw). The definition provides some examples but is not all inclusive. Some additional text has also been added in the explanatory statement. See response 40 in relation to Schedule 22 of the Code.
	Melon standard		
49	<ul style="list-style-type: none"> Only include rockmelons in standard – no evidence for other melons to be included. Increase focus on cut melons at retail 	Business	FSANZ's assessment is that the standards are commensurate with, and address, identified risks with primary production and processing of melons as a broader commodity group and not just rockmelons. The microbiological assessment outlines the risks of all melons in scope for the standard. Retail sale is already regulated through Chapter 3 standards. The standard relates to only primary production and processing.
50	<ul style="list-style-type: none"> Downgrade general food safety management requirements with notification only (since most melon businesses are on a FSS) 	Industry association	FSANZ's assessment identified that, even when businesses have FSS in place, outbreaks have continued to occur (SD1). The standards are based on identified hazards and provide an outcomes-based approach that is mandatory across all businesses, and which authorities can use to check measures are being correctly implemented.
	Flow-on impacts of regulation		
51	<ul style="list-style-type: none"> Remote businesses <ul style="list-style-type: none"> may face higher compliance (audit) costs; may have challenges with internet capacity, accessing water, assistance/expertise and repairs local government engagement in compliance will be limited regionally 	Government; Industry association; Individual	FSANZ acknowledges the challenges faced by remote businesses. Our assessment determined regulation is required to protect public health and provides an overall benefit (SD1 and SD2). Compliance and enforcement are matters for state and territory authorities and jurisdictions are actively considering appropriate tools and guidance and ways to reduce duplication of effort and costs where appropriate. Engagement and impact on local government is discussed at issue 7.
52	<ul style="list-style-type: none"> Small businesses <ul style="list-style-type: none"> extra fees and administration to comply and seek assistance will be unviable for many, they may not comply or may close down some businesses may switch to another (unregulated) commodity may see more consolidation of smaller operations into larger ones – and smaller businesses may be outcompeted or out priced 	Government; Industry association; Business; Individual	See response to issue 4. FSANZ notes for smaller businesses, HIWG have committed to develop a compliance approach with template tools and guidance, in consultation with industry.

53	<ul style="list-style-type: none"> For smaller businesses, HIWG have committed to develop a compliance approach with template tools and guidance, in consultation with industry 	Government	Noted.
54	<ul style="list-style-type: none"> Access to cheaper produce (berries) from farmers markets may drop, as producers supplying them (currently not all/any on a FSS) will no longer be able to sell at that price; other products will fill the gap 	Industry association	Noted. See response at issue 4.
55	<ul style="list-style-type: none"> May be flow-on strengthening of approved supplier systems prompted by producers 	Government	FSANZ agrees that this is a potential positive impact of introducing the standards that address critical food safety risks and incentivise food safety improvement through the entire supply chain.
56	<ul style="list-style-type: none"> Businesses not on FSS are likely to incur greatest costs and impact, but implementing a FSS could bring them benefits of accessing additional customers 	Industry association	Noted. The impacts for businesses not on a FSS were considered (see SD1 and SD2). See response at issue 4.
57	<ul style="list-style-type: none"> Wholesalers who accept fruit from growers not on a FSS may have less access to “cheap” product under the new requirements 	Industry association	Noted. This work focused on the protection of public health and addressing identified food safety risks. The standards provide base-level requirements to manage those risks. See SD1 and SD2 for further information.
58	<ul style="list-style-type: none"> May see price increases passed on down chain as growers will be unable to absorb costs; others believe unlikely to see prices increase so businesses will have to absorb costs 	Industry association; Business	Noted. See response at issue 57.
Implementation			
59	<ul style="list-style-type: none"> Need uniform adoption and a nationally consistent implementation approach <ul style="list-style-type: none"> industry calls on all jurisdictions to work with industry to minimise duplication especially for businesses working across jurisdictions government compliance plans developed indicate consistent approach, and extensive prior and ongoing work through HIWG including industry discussions 	Government; Industry association; Business	Agree. The standards enable a uniform national approach to food safety management. In assessing and approving these standards, FSANZ had regard to the costs and manner of implementation (see SD1 and SD2), noting that implementation remains a matter for the jurisdictions. FSANZ's understanding based on government advice and submissions is that jurisdictions have and are committed to working cooperatively with industry on implementation. They are working on a national approach, including a recognition model for certain FSS as part of a broader scheme of compliance tools and ways to reduce duplication of effort and cost.
60	<ul style="list-style-type: none"> Regulators will be (legally) required to verify a business's food safety arrangement meet requirements even if on FSS 	Government	Noted. This will be a matter for jurisdictions to determine.
61	<ul style="list-style-type: none"> Audit responsibility should not be delegated to a third party System should recognise role of third-party certification 	Industry association; Business	Noted. These are issues for jurisdictions and industry to consider in implementation.

62	<ul style="list-style-type: none"> Jurisdictions are committed to exploring recognition of GFSI-benchmarked schemes as way of demonstrating compliance with standards (including use of through-chain data monitoring) – this approach is expected to reduce duplication of effort for businesses and resource burden for regulators. Minimal additional burden is expected for businesses already on GFSI-FSS 	Government	Noted. These are issues for jurisdictions and industry to consider in implementation.
63	<ul style="list-style-type: none"> Implementation should consider different risks of products within commodity groups 	Government	Noted. These are issues for jurisdictions and industry to consider in implementation.
64	<ul style="list-style-type: none"> Need streamlined approach for businesses working across multiple jurisdictions. E.g. notification and FSMS requirements 	Industry association; Business	Noted. This will be a matter for jurisdictions to determine.
65	<ul style="list-style-type: none"> Resources should focus on producers not on FSS, and be developed with industry 	Industry association	Noted. Resources will be developed with the aim of increasing awareness of the standards and strengthening food safety culture for all businesses within scope.
66	<ul style="list-style-type: none"> FSANZ should assess implementation costs and efficacy 2 years post-implementation 	Industry association	FSANZ reviews its standards periodically. The Food Ministers Meeting may also at any time request FSANZ review one or more food standards.
67	<ul style="list-style-type: none"> Verification of compliance (for berries) could include evidence of FSS certification or a completed self-assessment of approved format 	Business	Noted. This will be a matter for jurisdictions to determine.
68	<ul style="list-style-type: none"> There should be no/minimal fee and administration for businesses already on a scheme 	Industry association; Business	Noted. This will be a matter for jurisdictions to determine.
69	<ul style="list-style-type: none"> A fee-free threshold should be set for any farm that sells direct to consumers; licence and audits should not be required 	Industry association	Noted. This will be a matter for jurisdictions to determine.
70	<ul style="list-style-type: none"> Government/water authorities will need to improve local water supplies, especially river water, and provide industry guidance on pre-harvest water quality requirements 	Business	Noted. This will be a matter for jurisdictions to determine.
71	<ul style="list-style-type: none"> Industry has challenges with supply and risk assessment of treated and composted waste 	Business	Noted. These are issues for jurisdictions and industry to consider in implementation.
72	<ul style="list-style-type: none"> Consider role of digital identification systems for traceability 	Business	Noted. This is an issue for jurisdictions and industry to consider in implementation.
Transition period			
73	<ul style="list-style-type: none"> Transition period should be at least 2, 2.5 or preferably 3 years to enable FSS owners, businesses and regulators to get everything 	Government; Industry association;	FSANZ has reconsidered the transition period and extended the time from 18 months to 2.5 years (30 months) based on stakeholder feedback, to provide time for government and industry to get the

	in place (incl. legislative changes, ICT and processes, resource development, training)	Business	necessary structures, processes and resources in place.
74	<ul style="list-style-type: none"> Appropriate time depends on how long it takes to produce non-regulatory supporting resources – (berry) businesses should have at least 6-12 months' time to implement 	Business	See response to issue 73.
75	<ul style="list-style-type: none"> Consider staggering introduction of the standards to enable legislation and systems to be adequately in place 	Government	See response to issue 73.
Non-regulatory/ educational resources			
76	<ul style="list-style-type: none"> Education and other non-regulatory measures are needed <ul style="list-style-type: none"> for primary producers and processors (especially smaller businesses and those not on a FSS), as well as distributors, wholesalers, retailers, and consumers on food safety obligations, best practice processes and food safety mind set/culture in multiple languages; variety of formats and delivery (more than FSANZ listed) e.g. online video training/ modules with nationally consistent messages and expectations to ensure ongoing collaboration and vigilance especially at key times e.g. extreme weather events with considerable investment 	Government; Industry association; Business	FSANZ agrees and has acknowledged the need for non-regulatory resources in identifying option 3 as the preferred option. FSANZ, government food regulators and industry representatives have been collaborating throughout the development of the standards, and will continue to do so for developing non-regulatory resources.
77	<ul style="list-style-type: none"> Need timeline and plan for developing and delivering non-regulatory resources to; ensure businesses and scheme owners have time to absorb before implementation begins 	Business	Noted. See response to issues 73-75.
78	<ul style="list-style-type: none"> Berry guidance template needs further information and guidance (with industry consultation) on best practice, especially since there is no FSMS requirement 	Government; Industry association; Business	FSANZ acknowledges HIWG's effort in developing the draft compliance plans and guidance template for stakeholder information and comment. FSANZ notes that HIWG has committed to developing and providing best practice resources, in collaboration with industry.
79	<ul style="list-style-type: none"> Jurisdictions aim to develop resources for businesses, particularly those not on a GFSI-FSS, to provide an alternate compliance model, especially for smaller businesses 	Government	Noted. See response to issue 76.
80	<ul style="list-style-type: none"> Government should work with industry; offers from industry to assist with developing/sharing 	Industry association; Business	Noted. See response to issue 76.

2.2 Microbiological assessment

FSANZ assessed [microbiological risks](#) associated with primary production and processing of fresh berries, leafy vegetables and melons in Australia. We also examined control measures to mitigate identified risks.

The main pathogens of concern for each commodity, in the Australian context, are:

- for berries: norovirus, shiga toxin-producing *Escherichia coli* (STEC) and hepatitis A virus (imported berries¹)
- for leafy vegetables: non-typhoidal *Salmonella* spp. (*Salmonella*), *Listeria monocytogenes* (*Listeria*) and STEC
- for melons: *Listeria* and *Salmonella*.

Left unmanaged, these pathogens can lead to mild to severe public health consequences. The most likely sources of contamination of berries, leafy vegetables and melons were identified. These include animals, growing location, extreme weather events, manure and composts, water inputs, postharvest washing and sanitisation, and poor worker and equipment hygiene. Multiple factors affect the level of contamination, and these factors vary between different products.

These fresh commodities are generally consumed raw, with little or no further processing. It is not possible to completely eliminate risk to consumers. Multiple controls are needed throughout the supply chain, but risk management needs to begin on farm.

There is no single step that can ensure product safety during production and processing. A range of control measures during primary production, harvest and postharvest activities were identified to minimise pathogen contamination of horticultural produce. These include applying good agricultural practices, good hygienic practices at harvest and postharvest, and controlling inputs through-chain.

The risks and control measures identified in the [microbiological assessment](#) formed the basis of FSANZ's consideration of appropriate risk management options.

2.3 Risk management

The risk management framework and process we used to guide our decisions is described below. Our assessment considered the expected impacts (positive, negative, direct and indirect) of four risk management options. Our full assessment is in the Decision Regulatory Impact Statement (DRIS) (SD1).

2.3.1 Risk management principles

FSANZ's risk management approach for this proposal is based on five principles (Table 2). These principles reflect our priority objective of protecting public health and safety in Australia, based on evidence. They also reflect development of a nationally consistent approach to safe food production of berries, leafy vegetables and melons, with minimal burden on industry.

¹ Hepatitis A virus is not assumed in the analysis to be a concern for domestically produced berries, only for some imported berries

Table 2. FSANZ risk management principles

Principle	Intended outcome
Protection of public health and safety	Reduction in foodborne illnesses attributed to berries, leafy vegetables and melons. Traceability requirements improve identifying and removing affected food, reducing cases of foodborne illness.
Cost-effective, minimal measures	Regulatory measures align with industry best practices, reducing impacts on businesses that already have best practice in place. Each proposed measure was designed to address critical risks and represents the lightest touch possible with an overall positive cost benefit ratio.
National consistency	All businesses meet a minimum level of food safety. There is a level playing field for all industry operations and requirements for managing food safety. Provides common accountability framework for all industry players, based on scientific risk. Allows for consistent implementation of national requirements. All food handlers, on farm and at initial processing stages, gain and apply the same level of food safety skills and knowledge. Australia maintains its reputation as a producer and exporter of safe food.
Best available scientific evidence	Our microbiological assessment considered the best scientific information currently available. We examined our previous assessments and updated data on Australian and international foodborne illness outbreaks associated with fresh horticultural produce, as well as related recall data. The Codex Code of Hygienic Practice for Fresh Fruits and Vegetables was also drawn upon to develop appropriate risk management measures.
Promotion of fair trading in food	Introduction of nationally consistent food safety requirements can encourage a more level playing field for all producers.

2.3.2 Risk management options

FSANZ developed four risk management options to address the food safety risks identified in the microbiological assessment:

- option 1 – Retaining the status-quo
- option 2 – Introducing regulatory measures
- option 3 – Introducing a combination of regulatory and non-regulatory measures
- option 4 – Introducing non-regulatory measures alone.

Each option was assessed against the criteria set out in section 59 of the FSANZ Act (see section 2.5). This assessment included a cost-benefit analysis (CBA; in SD2) of options 2–4 for each sector, comparing them against the status quo (option 1).

2.3.3 Rationale for option 3 as preferred approach

FSANZ has determined the preferred approach for all three sectors is government regulation supported by non-regulatory measures (option 3). The rationale for this option is underpinned by five key reasons:

- The problem is a major public health and safety issue.
- National application is the best approach to reduce foodborne illness.
- Regulation applies to all businesses in the sectors.
- Regulation aligns with and will be supported by existing industry food safety management measures.

- Regulation combined with non-regulation was found to have a positive net benefit in all three commodity groups.

The status quo was not our preferred option, as it does not adequately support public health and safety objectives—foodborne illness continues to be attributed to berries, leafy vegetables and melons. FSANZ acknowledges non-regulatory measures in industry—such as FSS, retailer requirements, codes of practice and other guidance—as important elements of food safety management. However, none of these measures are applied nationally across all primary production and processing businesses for the three commodities. FSANZ also notes that foodborne illness outbreaks involving horticultural produce have occurred even when businesses have had a FSS in place. This indicates that existing industry measures alone may not be adequate, or adequately implemented, to address the food safety risk.

The CBA found additional non-regulatory measures—such as further targeted guidance and education—to have some benefit as a standalone measure. However, there is a greater net benefit when regulation is combined with non-regulatory measures.

2.3.4 Proposed measures

As the assessment determined regulation to be appropriate and cost effective, FSANZ developed draft regulatory measures. We considered stakeholder feedback that any regulation be of minimal burden to industry. We designed requirements addressing critical food safety hazards identified in our microbiological assessment, while achieving a positive net benefit (when costs are assessed against reduced illness). The requirements closely align with food safety-related requirements in industry FSS, which are already in place for many businesses.

Three primary production and processing standards were drafted (one each for berries, leafy vegetables and melons) together with a related consequential variation to the Code. Separate standards (rather than a single one) were developed to reflect risk profiles specific for each commodity, which considered production and processing practices and the physical characteristics of the produce. In each case, the draft standard contains outcomes-based measures designed to manage known risks and causal factors of foodborne illness.

To support the standards, non-regulatory measures including fact sheets, webinars, and face-to-face meetings are also proposed. These would explain food safety risks and businesses' obligations, provide best practice guidance and improve food safety culture. These supporting measures would be developed collaboratively between government and industry during the transition period.

2.3.5 Finalising regulatory measures

The 2nd CFS sought stakeholder feedback on option 3 as our preferred approach and the three drafted standards and consequential variation (see section 2.1). Most stakeholders reaffirmed support for national measures to strengthen food safety in these sectors, and that they be the minimum required to manage the risk and create a level playing field. Most stakeholders, across government and conditional from industry, supported our preferred option of a combination of regulatory and non-regulatory measures.

In response to submissions and newly available evidence, FSANZ refined the CBA and reconsidered several aspects of the proposed standards. Several amendments were made to the standards, for improved clarity and to strengthen particular food safety measures.

For all three standards, the following changes were made:

- The transition period was extended from 18 months to 30 months, to enable ample time for regulators, businesses and FSS owners to prepare (including jurisdictional regulatory changes, information and communication technology, and processes, resource development, training).
- The Application section was amended to clarify the standards do not apply to manufacturing activities.
- The term ‘chopping’ was removed from the definitions of primary horticulture processor and relevant activities, to better delineate between activities related to Chapter 4 and Chapter 3 of the Code (the latter captures further processing activities).
- The term ‘storing’ was added to the definitions of primary horticulture processor and relevant activities, to identify storage as a key activity in primary production and processing, particularly modified atmosphere and refrigerated storage.

For the berries standard, the following additional amendments were made:

- The definition of berries was amended by removing ‘raspberries’ and including ‘berries of the genus *Rubus*’, to further clarify the scope of the standard and better capture the berries commonly grown in Australia.
- Soil amendments and fertilisers were added to the input management clause, to address risks specifically associated with berries grown close to ground.
- The traceability clause was amended to include identification of the growing site, to strengthen traceability in situations where berries are received from the same producer but from a different growing site/s.

For the leafy vegetables standard, the definition of leafy vegetables was amended to refer to any vegetables or herbs of a leafy nature where the leaf may be consumed raw, except seed sprouts. This amendment was made to provide clarity the standard applies to any vegetables used for fresh, raw foliar consumption other than seed sprouts. No amendment was made to the consequential variation.

Attachment A contains the approved draft standards and the approved draft consequential variation, and Attachment B provides the accompanying Explanatory Statements.

2.4 Risk communication

Risk communication, particularly with external stakeholders, is essential to inform our decision-making processes and ensure transparency in our standards development process.

Consultation is also a key part of FSANZ proposals. We developed and implemented a communication strategy for this proposal to consult with targeted stakeholders as well as the public.

2.4.1 Public consultations

FSANZ sought public comment through two calls for submissions, as required under the process for a major procedure. Subscribers and interested parties were notified about public consultation via the FSANZ Notification Circular, media releases and through our website, social media tools and Food Standards News.

The 1st CFS was held February–March 2020 and 27 responses were received. These submissions were taken into account in subsequent work and informed the decision summarised in our 2nd CFS report. The 2nd CFS was held November 2021–February 2022 and 32 submissions were received. These are summarised in Table 1 and were considered during our finalisation of the proposal and in approving the amended draft measures.

FSANZ acknowledges the time taken by individuals and organisations to make submissions on this proposal. Every submission was considered by FSANZ. All comments are valued and contributed to the rigour of our assessment.

2.4.2 Targeted stakeholder consultations

During 2019–early 2020, FSANZ held targeted consultations with industry and visited farms of each commodity group to understand industry practices and constraints. These visits further informed the development of draft regulatory measures. In December 2020–January 2021, FSANZ also surveyed berry, leafy vegetable and melon producers.

We also worked closely with the SDAG and HIWG, who provided expert advice throughout the proposal. FSANZ acknowledges the expertise of the members of both groups and their ongoing commitment to progress the work under this proposal.

2.4.3 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia is obliged to notify WTO members where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

FSANZ provided Sanitary and Phytosanitary (SPS) notification that Australia is reviewing food safety of primary production and processing in the berries, leafy vegetables and melons sectors, that will apply in Australia. Regulation of imported foods is the responsibility of DAWE. Any changes to the regulation of imported food products will be communicated by DAWE through a future SPS notification process. [FSANZ provides import risk advice](#) to DAWE on whether imported foods pose a potential medium or high risk to public health and safety. DAWE use this advice to manage food safety risks at the border. This proposal is unlikely to result in any changes to the current import conditions for food.

This proposal will not affect Australian biosecurity import conditions for these commodities.

2.5 FSANZ Act assessment requirements

2.5.1 Section 59

2.5.1.1 Consideration of costs and benefits

Paragraph 59(2)(a) of the FSANZ Act requires FSANZ to have regard to whether the costs that would arise from a proposed measure outweigh the direct or indirect benefits of the proposed measure. Our assessment is that the proposed draft standards and non-regulatory measures provide the greatest net benefit of the four risk management options we considered.

The full assessment, including of costs and benefits, is provided in the DRIS and CBA (see SD1 and SD2). The DRIS has been assessed by the Office of Best Practice Regulation (OBPR) as adequate to inform a final decision according to OBPR's guidelines; OBPR Reference: OBPR22-01822.

2.5.1.2 Other measures

Paragraph 59(2)(b) requires FSANZ to have regard to whether other measures (available to FSANZ or not) would be more cost-effective. We reviewed existing measures as part of

option 1 (status quo) and assessed a range of other plausible options. As noted in SD1, we consider the incomplete uptake of existing industry FSS and jurisdictional regulatory approaches do not adequately address the food safety issues. FSANZ's assessment is that the most cost-effective measure is adoption of standards combined with non-regulatory measures.

2.5.1.3 Any relevant New Zealand standards

Paragraph 59(2)(c) requires FSANZ to have regard to any relevant New Zealand standards. FSANZ notes the primary production and processing standards (Chapter 4) of the Code do not apply in New Zealand.

2.5.1.4 Any other relevant matters

Other relevant matters are considered below and in the SDs.

2.5.2. Subsection 18(1)

FSANZ has also considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

2.5.2.1 Protection of public health and safety

FSANZ assessed the available evidence and information on food safety risks and risk management measures currently applying to fresh berries, leafy vegetables and melons. Significant foodborne illness outbreaks associated with these sectors have occurred resulting in hundreds of illnesses and ten deaths since 2011 (outlined in the [microbiological assessment](#)). Investigations confirmed that outbreaks still occur even when businesses had FSS in place. FSANZ considers the current non-regulatory measures alone do not provide the necessary assurance that food safety risks are being addressed and public health and safety is protected.

2.5.2.2 The provision of adequate information relating to food to enable consumers to make informed choices

Consumers may be unaware that primary production and primary processing of these commodities is not regulated, or that some businesses participate in FSS, while others do not. As such, they are unable to take this into consideration when making safe food choices.

2.5.2.3 The prevention of misleading or deceptive conduct

FSANZ has not identified any issues relevant to this objective.

2.5.3 Subsection 18(2) considerations

FSANZ has also had regard to:

- **the need for standards to be based on risk analysis using the best available scientific evidence**

FSANZ's [microbiological assessment](#) and CBA (SD2) considered the best scientific information currently available. We examined our assessments and updated data on Australian and international foodborne illness outbreaks associated with fresh horticultural produce (see section 2.2), as well as related recall data. The Codex Code of Hygienic Practice for Fruits and Vegetables was also drawn upon to develop appropriate risk management measures.

- **the promotion of consistency between domestic and international food standards**

Internationally, there is wide variation in the legislation applicable to the production of horticultural produce. We considered international and domestic standards in our assessment, including requirements for import and export of food. Refer to the DRIS (SD1) (and SD1 of the 2nd CFS).

- **the desirability of an efficient and internationally competitive food industry**

FSANZ has had regard to the public health and safety risks associated with the three horticulture sectors and possible impact of these risks on the domestic and international food industry (SD2, Appendix 6).

FSANZ does not anticipate any significant impact on efficiency and international competition from introduction of any proposed regulatory measure; see SD1 and SD2 for more information.

- **the promotion of fair trading in food**

Introduction of nationally consistent food safety requirements can encourage a more level playing field for all primary producers and primary processors of these commodities in the market place (see SD1).

- **any written policy guidelines formulated by the Forum on Food Regulation**

The Ministerial Council Overarching Policy Guideline on Primary Production and Processing Standards² contains high-order principles that must be considered when a standard is developed. These principles state that standards will be outcomes based and address food safety across the entire food chain where appropriate. Standards will also ensure the cost of the overall system is proportionate with the assessed level of risk. They will provide a regulatory framework that only applies to the extent justified by market failure. We have considered these guidelines in our assessment.

3 Transitional arrangements

A 30-month implementation period will be in effect from the date of gazettal for all three standards. The draft approved standards will not commence or take effect until after this period.

4 Implementation

FSANZ had regard to implementation costs in its assessment. See, for example, sections 2.1 and 2.5.1.1 of this report and SD1 (DRIS) and SD2 (CBA). How the approved draft standards are implemented remains a matter for the jurisdictions to determine. FSANZ's understanding is that jurisdictions have yet to agree on a model for implementation and have committed to work with industry in developing a model. When developing its cost and benefit estimates, FSANZ considered implementation costs such as those associated with rights of entry, licensing, registration and audit to account for the possibility that they may form part of the implementation model adopted by jurisdictions. The draft standards approved by FSANZ do not contain or impose such requirements (for example, Standard 4.2.7 imposes a notification

² Available at <https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/food-policies>

requirement only).

However, in assessing the costs and benefits of the draft standards, FSANZ estimated and had regard to these type of costs to account for the possibility that they may form part of the implementation model adopted by jurisdictions.

Implementation of the standards is the responsibility of the states and territories. ISFR facilitates the consistent national implementation of standards by developing agreed approaches and compliance materials.

The HIWG was established by ISFR for this purpose. This proposal progressed using the [Integrated Model for Standards Development and Consistent Implementation of Primary Production and Processing Standards](#)³.

Draft compliance plans and guidance were developed by the HIWG and published with the 2nd CFS to provide examples of what each proposed standard—if endorsed by the Food Ministers Meeting—would look like at a practical level and to seek stakeholder feedback. Relevant submissions from stakeholders have been shared with the HIWG for their consideration. Implementation plans will be further developed and refined by state and territory food regulators during the transition period, in conjunction with industry, FSS owners and FSANZ.

Attachments

- A. Approved draft variations to the *Australia New Zealand Food Standards Code*
- B. Approved Explanatory Statement
- C. Draft variations to the *Australia New Zealand Food Standards Code* (as provided in the 2nd Call for submissions)

³ <https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/ISFR>

Attachment A – Approved draft variations to the *Australia New Zealand Food Standards Code*

This Attachment contains the following approved draft measures:

- Standard 4.2.7 Primary Production and Processing Standard for Berries
- Standard 4.2.8 Primary Production and Processing Standard for Leafy Vegetables
- Standard 4.2.9 Primary Production and Processing Standard for Melons
- Food Standards (Proposal P1052 – Primary Production and Processing Requirements for Horticulture (Berries, Leafy Vegetables and Melons) – Consequential Amendments) Variation

Standard 4.2.7 – Primary Production and Processing Standard for Berries

The Board of Food Standards Australia New Zealand gives notice of the making of this Standard under section 92 of the *Food Standards Australia New Zealand Act 1991*. The Standard commences on a date 30 months after the date of gazettal.

Dated [To be completed by the Delegate]

[Name of Delegate]

Delegate of the Board of Food Standards Australia New Zealand

Note:

This Standard will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX. This means that this date is the gazettal date for the purposes of the above notice.

Standard 4.2.7 Primary Production and Processing Standard for Berries

Note 1 This instrument is a standard under the *Food Standards Australia New Zealand Act 1991* (Cth). The standards together make up the *Australia New Zealand Food Standards Code*. See also section 1.1.1—3.

Note 2 This Standard applies in Australia only.

Division 1 Preliminary

4.2.7—1 Name

This Standard is *Australia New Zealand Food Standards Code – Standard 4.2.7 – Primary Production and Processing Standard for Berries*.

Note Commencement:
This Standard commences on a date 30 months after the date of gazettal, being the date specified as the commencement date in notices in the *Gazette* and the *New Zealand Gazette* under section 92 of the *Food Standards Australia New Zealand Act 1991* (Cth). See also section 93 of that Act.

4.2.7—2 Definitions

In this Standard:

berries means fresh berries; and includes strawberries, blueberries, and berries from the genus *Rubus*.

growing site means any site used to grow berries; and includes an open, partially enclosed or enclosed planting area.

harvest means all activities related to the collection and removal of berries from a growing site; and includes picking, cutting, field packing (including packaging for retail sale), and transport from the growing site to the next step in the supply chain.

premises and equipment means equipment, infrastructure, structures and vehicles that:

- (a) are used by a primary horticulture producer or by a primary horticulture processor; and
- (b) have direct or indirect contact with berries.

primary horticulture producer means a business, enterprise or activity that involves the growing and/or harvesting of berries.

primary horticulture processor means a business, enterprise or activity that involves one or more of the following activities in relation to berries that have been harvested:

- (a) washing;
- (b) trimming;
- (c) sorting;
- (d) sanitising;
- (e) storing;
- (f) combining harvested berries;
- (g) packing; and
- (h) transport between primary processing premises.

relevant activity means:

- (a) in relation to a primary horticulture producer, the growing and/or harvesting

- of berries; and
- (b) in relation to a primary horticulture processor, any of the following:
- (i) washing harvested berries;
 - (ii) trimming harvested berries;
 - (iii) sorting harvested berries;
 - (iv) sanitising harvested berries;
 - (v) storing harvested berries;
 - (vi) combining harvested berries;
 - (vii) packing harvested berries; and
 - (viii) transporting harvested berries between primary processing premises.

Note 1 In this Code (see section 1.1.2—2(3) of Standard 1.1.2)

relevant authority means an authority responsible for the enforcement of the relevant application Act

Note 2 In this Chapter (see clause 1 of Standard 4.1.1):

inputs includes any feed, litter, water (including recycled water), chemicals or other substances used in, or in connection with, the primary production or processing activity.

Note 3 Clause 3 of Standard 4.1.1 sets out when a food will be unacceptable for the purposes of this Standard.

4.2.7—3 Application

- (1) This Standard applies to primary horticulture producers and to primary horticulture processors in Australia.
- (2) This Standard does not apply to the retail sale of berries.
- (3) This Standard does not apply to manufacturing of harvested berries which includes the cooking, freezing, drying, preserving, blending or juicing of harvested berries or the addition of other foods to harvested berries.

4.2.7—4 Notification

- (1) A primary horticulture producer and a primary horticulture processor must provide the specified information to the relevant authority before engaging in a relevant activity.
- (2) In this section, **specified information** means the following information:
 - (a) the contact details of the primary horticulture producer or the primary horticulture processor, including the name of their business and the name and business address of the proprietor of their business;
 - (b) a description of the activities the primary horticulture producer or the primary horticulture processor will undertake in relation to berries; and
 - (c) the location or locations of each activity referred to in paragraph (b) that is within the jurisdiction of the relevant authority.
- (3) A primary horticulture producer and a primary horticulture processor must notify the relevant authority of any proposed change to specified information provided to a relevant authority in accordance with this section before that change occurs.

4.2.7—5 Traceability

A primary horticulture producer and a primary horticulture processor must have in place a system that can identify:

- (a) the growing site of berries which they grew or received; and

- (b) from whom berries were received; and
- (c) to whom berries were supplied.

4.2.7—6 Inputs – soil, fertiliser and water

A primary horticulture producer and a primary horticulture processor must take all reasonable measures to ensure that any of the following inputs do not make berries unacceptable:

- (a) soil;
- (b) soil amendments (including manure, human biosolids, compost, and plant bio-waste);
- (c) fertiliser; and
- (d) water.

4.2.7—7 Premises and equipment

- (1) A primary horticulture producer and a primary horticulture processor must take all reasonable measures to ensure that premises and equipment are designed, constructed, maintained and operated in a way that:
 - (a) allows for effective cleaning and sanitisation of the premises and equipment; and
 - (b) does not make berries unacceptable.
- (2) A primary horticulture producer and a primary horticulture processor must ensure that premises and equipment are kept clean, sanitised and in good repair to the extent required to ensure that berries are not made unacceptable.

4.2.7—8 Skills and knowledge

A primary horticulture producer and a primary horticulture processor must ensure that persons who engage in a relevant activity, or who supervise a person who engages in a relevant activity, have:

- (a) knowledge of food safety and food hygiene matters; and
- (b) skills in food safety and food hygiene matters commensurate with their work.

4.2.7—9 Health and hygiene of personnel and visitors

A primary horticulture producer and a primary horticulture processor must take all reasonable measures to ensure that personnel and visitors exercise personal hygiene and health practices that do not make berries unacceptable.

4.2.7—10 Sale or supply of unacceptable berries

A primary horticulture producer and a primary horticulture processor must not sell or supply berries for human consumption if they ought reasonably know, or ought reasonably suspect, that the berries are unacceptable.

Standard 4.2.8 – Primary Production and Processing Standard for Leafy Vegetables

The Board of Food Standards Australia New Zealand gives notice of the making of this Standard under section 92 of the *Food Standards Australia New Zealand Act 1991*. The Standard commences on a date 30 months after the date of gazettal.

Dated [To be completed by the Delegate]

[Name of Delegate]

Delegate of the Board of Food Standards Australia New Zealand

Note:

This Standard will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX. This means that this date is the gazettal date for the purposes of the above notice.

Standard 4.2.8 Primary Production and Processing Standard for Leafy Vegetables

Note 1 This instrument is a standard under the *Food Standards Australia New Zealand Act 1991* (Cth). The standards together make up the *Australia New Zealand Food Standards Code*. See also section 1.1.1—3.

Note 2 This Standard applies in Australia only.

Division 1 Preliminary

4.2.8—1 Name

This Standard is *Australia New Zealand Food Standards Code – Standard 4.2.8 – Primary Production and Processing Standard for Leafy Vegetables*.

Note Commencement:
This Standard commences on a date 30 months after the date of gazettal, being the date specified as the commencement date in notices in the *Gazette* and the *New Zealand Gazette* under section 92 of the *Food Standards Australia New Zealand Act 1991* (Cth). See also section 93 of that Act.

4.2.8—2 Definitions

In this Standard:

leafy vegetables means vegetables of a leafy nature where the leaf is consumed raw; and includes baby leaves, lettuce, and leafy herbs; and does not include seed sprouts.

growing site means any site used to grow leafy vegetables; and includes an open, partially enclosed or enclosed planting area.

harvest means all activities related to the collection and removal of leafy vegetables from a growing site; and includes picking, cutting, field packing (including packaging for retail sale), and transport from the growing site to the next step in the supply chain.

premises and equipment means equipment, infrastructure, structures and vehicles that:

- (a) are used by a primary horticulture producer or by a primary horticulture processor; and
- (b) have direct or indirect contact with leafy vegetables.

primary horticulture producer means a business, enterprise or activity that involves the growing and/or harvesting of leafy vegetables.

primary horticulture processor means a business, enterprise or activity that includes one or more of the following activities in relation to leafy vegetables that have been harvested:

- (a) washing;
- (b) trimming;
- (c) sorting;
- (d) sanitising;
- (e) storing;
- (f) combining harvested leafy vegetables;
- (g) packing; and
- (h) transport between primary processing premises.

relevant activity means:

- (a) in relation to a primary horticulture producer, the growing and/or harvesting of leafy vegetables; and
- (b) in relation to a primary horticulture processor, any of the following:
 - (i) washing harvested leafy vegetables;
 - (ii) trimming harvested leafy vegetables;
 - (iii) sorting harvested leafy vegetables;
 - (iv) sanitising harvested leafy vegetables;
 - (v) storing harvested leafy vegetables;
 - (vi) combining harvested leafy vegetables;
 - (vii) packing harvested leafy vegetables; and
 - (viii) transporting harvested leafy vegetables between primary processing premises.

Note 1 In this Chapter (see clause 1 of Standard 4.1.1):

general food safety management requirements means the requirements in Division 2 of Standard 4.1.1.

inputs includes any feed, litter, water (including recycled water), chemicals or other substances used in, or in connection with, the primary production or processing activity.

Note 2 Clause 3 of Standard 4.1.1 sets out when a food will be unacceptable for the purposes of this Standard.

4.2.8—3 Application

- (1) This Standard applies to primary horticulture producers and to primary horticulture processors in Australia.
- (2) This Standard does not apply to the retail sale of leafy vegetables.
- (3) This Standard does not apply to manufacturing of harvested leafy vegetables which includes the cooking, freezing, drying, preserving, blending or juicing of harvested leafy vegetables or the addition of other foods to harvested leafy vegetables.

4.2.8—4 General food safety management requirements

A primary horticulture producer and a primary horticulture processor must comply with the general food safety management requirements.

4.2.8—5 Traceability

A primary horticulture producer and a primary horticulture processor must have in place a system that can identify:

- (a) from whom leafy vegetables were received; and
- (b) to whom leafy vegetables were supplied.

4.2.8—6 Inputs – seed, seedling, soil, fertiliser and water

A primary horticulture producer and a primary horticulture processor must take all reasonable measures to ensure that any of the following inputs do not make leafy vegetables unacceptable:

- (a) seeds;
- (b) seedlings;
- (c) soil;
- (d) soil amendments (including manure, human biosolids, compost, and plant bio-waste);
- (e) fertiliser; and

(f) water.

4.2.8—7 Growing sites

A primary horticulture producer must take all reasonable measures to ensure that a growing site is located, designed, constructed, maintained and operated such that leafy vegetables are not made unacceptable.

4.2.9—8 Weather events

A primary horticulture producer and a primary horticulture processor must take appropriate remedial action to ensure that leafy vegetables adversely affected by weather conditions are not unacceptable.

4.2.8—9 Premises and equipment

- (1) A primary horticulture producer and a primary horticulture processor must take all reasonable measures to ensure that premises and equipment are designed, constructed, maintained and operated in a way that:
 - (a) allows for effective cleaning and sanitisation of the premises and equipment; and
 - (b) does not make leafy vegetables unacceptable.
- (2) A primary horticulture producer and a primary horticulture processor must ensure that premises and equipment are kept clean, sanitised and in good repair to the extent required to ensure that leafy vegetables are not made unacceptable.

4.2.8—10 Temperature of harvested leafy vegetables

A primary horticulture producer and a primary horticulture processor must keep harvested leafy vegetables at a temperature that does not make the leafy vegetables unacceptable.

4.2.8—11 Washing and sanitisation of harvested leafy vegetables

A primary horticulture processor must take all reasonable measures to ensure that:

- (a) visible extraneous material on harvested leafy vegetables is removed; and
- (b) any washing or sanitising of harvested leafy vegetables does not make the leafy vegetables unacceptable.

4.2.8—12 Animals and pests

A primary horticulture producer and a primary horticulture processor must take all reasonable measures to minimise the presence of animals, vermin and pests in growing sites, and in premises and equipment, to ensure that leafy vegetables are not made unacceptable.

4.2.8—13 Skills and knowledge

A primary horticulture producer and a primary horticulture processor must ensure that persons who engage in a relevant activity, or who supervise a person who engages in a relevant activity, have:

- (a) knowledge of food safety and food hygiene matters; and
- (b) skills in food safety and food hygiene matters

commensurate with their work.

4.2.8—14 Health and hygiene of personnel and visitors

A primary horticulture producer and a primary horticulture processor must take all reasonable measures to ensure that personnel and visitors exercise personal hygiene and health practices that do not make leafy vegetables unacceptable.

4.2.8—15**Sale or supply of unacceptable leafy vegetables**

A primary horticulture producer and a primary horticulture processor must not sell or supply leafy vegetables for human consumption if they ought reasonably know, or ought reasonably suspect, that the leafy vegetables are unacceptable.

Standard 4.2.9 – Primary Production and Processing Standard for Melons

The Board of Food Standards Australia New Zealand gives notice of the making of this Standard under section 92 of the *Food Standards Australia New Zealand Act 1991*. The Standard commences on a date 30 months after the date of gazettal.

Dated [To be completed by the Delegate]

[Name of Delegate]

Delegate of the Board of Food Standards Australia New Zealand

Note:

This Standard will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX. This means that this date is the gazettal date for the purposes of the above notice.

Standard 4.2.9 Primary Production and Processing Standard for Melons

Note 1 This instrument is a standard under the *Food Standards Australia New Zealand Act 1991* (Cth). The standards together make up the *Australia New Zealand Food Standards Code*. See also section 1.1.1—3.

Note 2 This Standard applies in Australia only.

Division 1 Preliminary

4.2.9—1 Name

This Standard is *Australia New Zealand Food Standards Code – Standard 4.2.9 – Primary Production and Processing Standard for Melons*.

Note Commencement:
This Standard commences on a date 30 months after the date of gazettal, being the date specified as the commencement date in notices in the *Gazette* and the *New Zealand Gazette* under section 92 of the *Food Standards Australia New Zealand Act 1991* (Cth). See also section 93 of that Act.

4.2.9—2 Definitions

In this Standard:

melons means fresh melons; and includes watermelon, rockmelon, honeydew melon, and piel de sapo.

growing site means any site used to grow melons; and includes an open, partially enclosed or enclosed planting area.

harvest means all activities related to the collection and removal of melons from a growing site; and includes picking, cutting, field packing (including packaging for retail sale), and transport from the growing site to the next step in the supply chain.

premises and equipment means equipment, infrastructure, structures and vehicles that:

- (a) are used by a primary horticulture producer and a primary horticulture processor; and
- (b) have direct or indirect contact with melons.

primary horticulture producer means a business, enterprise or activity that involves the growing and/or harvesting of melons.

primary horticulture processor means a business, enterprise or activity that involves one or more of the following activities in relation to melons that have been harvested:

- (a) washing;
- (b) trimming;
- (c) sorting;
- (d) sanitising;
- (e) storing;
- (f) combining harvested melons;
- (g) packing; and
- (h) transport between primary processing premises.

relevant activity means:

- (a) in relation to a primary horticulture producer, the growing and/or harvesting

- of melons; and
- (b) in relation to a primary horticulture processor, any of the following:
- (i) washing harvested melons;
 - (ii) trimming harvested melons;
 - (iii) sorting harvested melons;
 - (iv) sanitising harvested melons;
 - (v) storing harvested melons;
 - (vi) combining harvested melons;
 - (vii) packing harvested melons; and
 - (viii) transporting harvested melons between primary processing premises.

Note 1 In this Chapter (see clause 1 of Standard 4.1.1):

general food safety management requirements means the requirements in Division 2 of Standard 4.1.1.

inputs includes any feed, litter, water (including recycled water), chemicals or other substances used in, or in connection with, the primary production or processing activity.

Note 2 Clause 3 of Standard 4.1.1 sets out when a food will be unacceptable for the purposes of this Standard.

4.2.9—3 Application

- (1) This Standard applies to primary horticulture producers and to primary horticulture processors in Australia.
- (2) This Standard does not apply to the retail sale of melons.
- (3) This Standard does not apply to manufacturing of harvested melons which includes the cooking, freezing, drying, preserving, blending or juicing of harvested melons or the addition of other foods to harvested melons.

4.2.9—4 General food safety management requirements

A primary horticulture producer and a primary horticulture processor must comply with the general food safety management requirements.

4.2.9—5 Traceability

A primary horticulture producer and a primary horticulture processor must have in place a system that can identify:

- (a) from whom melons were received; and
- (b) to whom melons were supplied.

4.2.9—6 Inputs – soil, fertiliser and water

A primary horticulture producer and a primary horticulture processor must take all reasonable measures to ensure that any of the following inputs do not make the melons unacceptable:

- (a) soil;
- (b) soil amendments (including manure, human biosolids, compost, and plant bio-waste);
- (c) fertiliser; and
- (d) water.

4.2.9—7 Growing sites

A primary horticulture producer must take all reasonable measures to ensure that a growing site is located, designed, constructed, maintained and operated such that

melons are not made unacceptable.

4.2.9—8 Weather events

A primary horticulture producer and a primary horticulture processor must take appropriate remedial action to ensure that melons adversely affected by weather conditions are not unacceptable.

4.2.9—9 Premises and equipment

- (1) A primary horticulture producer and a primary horticulture processor must take all reasonable measures to ensure that premises and equipment are designed, constructed, maintained and operated in a way that:
 - (a) allows for effective cleaning and sanitisation of the premises and equipment; and
 - (b) does not make melons unacceptable.
- (2) A primary horticulture producer and a primary horticulture processor must ensure that premises and equipment are kept clean, sanitised and in good repair to the extent required to ensure that melons are not made unacceptable.

4.2.9—10 Temperature of harvested melons

A primary horticulture producer and a primary horticulture processor must keep harvested melons at a temperature that does not make the melons unacceptable.

4.2.9—11 Washing and sanitisation of harvested melons

A primary horticulture processor must take all reasonable measures to ensure that:

- (a) visible extraneous material on harvested melons is removed; and
- (b) any washing or sanitising of harvested melons does not make the melons unacceptable.

4.2.9—12 Animals and pests

A primary horticulture producer and a primary horticulture processor must take all reasonable measures to minimise the presence of animals, vermin and pests in growing sites, and in premises and equipment, to ensure that melons are not made unacceptable.

4.2.9—13 Skills and knowledge

A primary horticulture producer and a primary horticulture processor must ensure that persons who engage in a relevant activity, or who supervise a person who engages in a relevant activity, have:

- (c) knowledge of food safety and food hygiene matters; and
- (d) skills in food safety and food hygiene matters

commensurate with their work.

4.2.9—14 Health and hygiene of personnel and visitors

A primary horticulture producer and a primary horticulture processor must take all reasonable measures to ensure that personnel and visitors exercise personal hygiene and health practices that do not make melons unacceptable.

4.2.9—15 Sale or supply of unacceptable melons

A primary horticulture producer and a primary horticulture processor must not sell or supply melons for human consumption if they ought reasonably know, or ought reasonably suspect, that the melons are unacceptable.



Food Standards (Proposal P1052 – Primary Production and Processing Requirements for Horticulture (Berries, Leafy Vegetables and Melons) – Consequential Amendments) Variation

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The variation commences on the date specified in clause 3 of this variation.

Dated [To be completed by the Delegate]

[Name of Delegate]

Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX. This means that this date is the gazettal date for the purposes of the above notice.

1 Name

This instrument is the *Food Standards (Proposal P1052 – Primary Production and Processing Requirements for Horticulture (Berries, Leafy Vegetables and Melons) – Consequential Amendments) Variation*.

2 Variation to Standards in the *Australia New Zealand Food Standards Code*

The Schedule varies a Standard in the *Australia New Zealand Food Standards Code*.

3 Commencement

The Variation commences immediately after all of the following Standards have commenced:

- (a) Standard 4.2.7;
- (b) Standard 4.2.8;
- (c) Standard 4.2.9.

SCHEDULE

Standard 1.1.1—Structure of the Code and general provisions

[1] Subsection 1.1.1—2(2)

Omit:

Standard 4.2.6 Production and Processing Standard for Seed Sprouts

Substitute:

Standard 4.2.6 Production and Processing Standard for Seed Sprouts

Standard 4.2.7 Primary Production and Processing Standard for Berries

Standard 4.2.8 Primary Production and Processing Standard for Leafy Vegetables

Standard 4.2.9 Primary Production and Processing Standard for Melons

Attachment B - Explanatory Statements

Standard 4.2.7 – Primary Production and Processing Standard for Berries

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 2 of Part 3 of the FSANZ Act specifies that the Authority may prepare a proposal for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering a proposal for the development or variation of food regulatory measures.

The Authority prepared Proposal P1052 – Primary Production and Processing requirements for Horticulture (berries, leafy vegetables and melons). The Authority considered the Proposal in accordance with Division 2 of Part 3 and has approved a number of draft measures including Standard 4.2.7 – *Primary Production and Processing Standard for Berries*.

2. Standard is a legislative instrument

The approved draft Standard is a legislative instrument for the purposes of the *Legislation Act 2003* (see section 94 of the FSANZ Act) and is publicly available on the Federal Register of Legislation (www.legislation.gov.au).

This instrument is not subject to the disallowance or sunset provisions of the *Legislation Act 2003*. Subsections 44(1) and 54(1) of that Act provide that a legislative instrument is not disallowable or subject to sunset if the enabling legislation for the instrument (in this case, the FSANZ Act): (a) facilitates the establishment or operation of an intergovernmental scheme involving the Commonwealth and one or more States; and (b) authorises the instrument to be made for the purposes of the scheme. Regulation 11 of the *Legislation (Exemptions and other Matters) Regulation 2015* also exempts from sunset legislative instruments a primary purpose of which is to give effect to an international obligation of Australia.

The FSANZ Act gives effect to an intergovernmental agreement (the Food Regulation Agreement) and facilitates the establishment or operation of an intergovernmental scheme (national uniform food regulation). That Act also gives effect to Australia's obligations under an international agreement between Australia and New Zealand. For these purposes, the Act establishes the Authority to develop food standards for consideration and endorsement by the Food Ministers Meeting (FMM). The FMM is established under the Food Regulation Agreement and the international agreement between Australia and New Zealand, and consists of New Zealand, Commonwealth and State/Territory members. If endorsed by the FMM, the food standards on gazettal and registration are incorporated into and become part of Commonwealth, State and Territory and New Zealand food laws. These standards or instruments are then administered, applied and enforced by these jurisdictions' regulators as part of those food laws.

3. Purpose

The Authority approved the draft Standard to minimise food safety risks associated with the primary production and processing of fresh berries in Australia.

Berries contaminated by pathogenic microorganisms present an unacceptable health risk to consumers. In recent years, outbreaks of foodborne illness have been associated with the consumption of berries both in Australia and overseas.

The food regulatory measures in the approved draft Standard, along with existing measures in the Code, address the public health and safety problem identified with berries in the most cost-effective manner.

4. Documents incorporated by reference

The approved draft Standard does not incorporate any documents by reference.

5. Consultation

In accordance with the procedure in Division 2 of Part 3 of the FSANZ Act, the Authority's consideration of Proposal P1052 included two rounds of public consultation following an assessment, targeted communication with key stakeholders, and the preparation of three draft standards and associated assessment summaries.

The first call for submissions was held between February and March 2020. Targeted consultation was undertaken in December 2020–January 2021. The second call for submissions was held between November 2021 and February 2022.

A Standards Development Advisory Group was established with representatives from the industry sector and State, Territory and federal government agencies to provide ongoing advice to FSANZ throughout the standard development process. A Horticulture Implementation Working Group comprised of State, Territory and federal government regulators was established by the Implementation Sub-committee for Food Regulation to work with FSANZ and ensure a nationally consistent approach to implementation of the standards.

A Decision Regulation Impact Statement (DRIS) was prepared by the Authority and has been approved by The Office of Best Practice Regulation (Reference - OBPR22-01822).

6. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the *Legislation Act 2003*.

7. Approved Draft Standard

Standard 4.2.7 is a new Standard to be incorporated into the Code. The purpose of each provision in the Standard is explained below

Note 1 explains that the instrument is a standard under the FSANZ Act, and that the Standard and the other standards together make up the Code.

Note 2 explains that the Standard applies only in Australia.

Section 1: This section establishes that the name of the instrument is the *Australia New Zealand Food Standards Code – Standard 4.2.7 – Primary Production and Processing Standard for Berries*.

The note to section 1 explains that the Standard will commence on the date that is 30 months following the date of gazettal, being the date specified in accordance with section 92 of the FSANZ Act.

Section 2: This section sets out the definitions for key words and phrases used in the Standard, or signposts to where those definitions are provided in other standards in the Code.

Berries means fresh berries and includes strawberries, blueberries, and berries of the genus *Rubus*. The definition is inclusive in that the specific products listed in it are intended as examples of berries, rather than constituting an exhaustive list.

Growing site means any site used to grow berries; and includes an open, partially enclosed or enclosed planting area. The definition clarifies that the Standard applies to open fields as well as other cropping arrangements in fully or partially enclosed structures, such as hydroponic set ups.

Harvest means all activities related to the collection and removal of berries from a growing site; and includes picking, cutting, field packing (including packaging for retail sale), and transport from the growing site to the next step in the supply chain.

Premises and equipment means equipment, infrastructure, structures and vehicles that: are used by a primary horticulture producer or by a primary horticulture processor; and have direct or indirect contact with berries. Examples of 'indirect contact' include pipes used to carry irrigation water, and equipment that may be placed on a food contact surface.

Primary horticulture producer means a business, enterprise or activity that is involved in the growing and / or harvesting of berries.

Primary horticulture processor means a business, enterprise or activity that is involved in one or more of the following activities in relation to berries, that have been harvested: washing, trimming, sorting, sanitising, storing, combining products, packing, and transport between primary processing premises. Primary processing is intended to include minimal post-harvest processing activities and does not include further processing or manufacturing activities such as freezing, drying, cooking, canning or blending berries with other ingredients. Transport other than transport from primary processing facilities is not included. Chapter 3 would already apply to these further processing and transport activities.

Relevant activity means, in relation to a primary horticulture producer, the growing and/or harvesting of berries. In relation to a primary horticulture processor, relevant activities mean the following activities with harvested berries: washing, trimming, sorting, sanitising, storing, combining products, packing, and transport between primary processing premises. The definition is provided to clarify which activities relate to certain requirements in the Standard. Primary processing relevant activities are intended to include minimal post-harvest processing activities and not to include further processing or manufacturing activities such as freezing, drying, cooking, canning or blending berries with other ingredients. Chapter 3 would already apply to these further processing activities. Transport other than transport from primary processing facilities is not included in the definition. Chapter 3 would already apply to these transport activities.

The Notes to section 4.2.7—2 signpost relevant definitions contained in other parts of the Code. Note 1 refers readers to the definition of *relevant authority* in section 1.1.2—2(3). Note

2 refers readers to the definition of *inputs* in clause 1 of Standard 4.1.1. Note 3 refers readers to clause 3 of Standard 4.1.1, which sets out when a food will be unacceptable for the purposes of the Standard.

Section 3: This provision deals with the application of the Standard.

Subsection (1) provides that the Standard applies only to primary horticulture producers and primary horticulture processors in Australia. The Standard does not apply to activities that are not captured by the definition of ‘primary horticulture producer’ and of ‘primary horticulture processor’.

Subsection (2) provides that the Standard does not apply to the retail sale of berries. Chapter 3 of the Code already applies to retail activities.

Subsection (3) provides that the Standard does not apply to manufacturing activities of harvested berries, which include but are not limited to cooking, freezing, drying, preserving, blending or juicing of harvested berries or the addition of other foods to harvested berries. Chapter 3 of the Code already applies to manufacturing activities.

Section 4: This provision sets out notification requirements for primary horticulture producers and primary horticulture processors of berries.

Subsection 4.2.7—4(1) requires a primary horticulture producer and a primary horticulture processor to provide **specified information** to the relevant authority of business activities related to berries, before engaging in a relevant activity. The term ‘relevant activity’ is defined by section 4.2.7—2.

Subsection 4.2.7—4(2) sets out what ‘specified information’ means for the purposes of the section. It means:

- the contact details of the primary horticulture producer or primary horticulture processor including the name of their business and the name and business address of the proprietor of their business; and
- a description of activities that the primary horticulture producer or primary horticulture processor will undertake in relation to berries; and
- the location or locations of each of the above-mentioned activities that are within the jurisdiction of the relevant authority.

Subsection 4.2.7—4(3) requires a primary horticulture producer or a primary horticulture processor to update their notified specified information. If a primary horticulture producer or a primary horticulture processor changes their notified contact details, activities relating to berries and/or the location of such activities as described, they must notify the relevant authority before that change occurs.

Section 5: This provision requires a primary horticulture producer and a primary horticulture processor to have a system in place that identifies the growing site of berries which they grew or received, and from whom berries were received, and to whom they were supplied (with retail sale excluded). The intent is that the system would enable the business to trace the produce one step back and one step forward, as a minimum. The requirement includes identification of the growing site to provide traceability to a specific site if berries are grown by or received from a business that has multiple growing sites. The required information will enable a rapid response and removal of unsafe produce if a food safety issue arises and/or a product recall is required.

Section 6: This provision requires a primary producer and a primary processor of berries to take all reasonable measures to ensure inputs do not make berries unacceptable. The

specified inputs are soil, soil amendments (including manure, human biosolids, compost, and plant bio-waste), fertilisers and water. 'Water' is intended to include recycled water, but is not intended to include falling rain.

Section 7: These provisions deal with premises and equipment. Subsection (1) requires a primary horticulture producer and a primary horticulture processor to take all reasonable measures to ensure that premises and equipment are designed, constructed, maintained and operated in a way that allows for effective cleaning and sanitisation of the premises and equipment; and does not make berries unacceptable. Subsection (2) of each provision requires a primary horticulture producer and a primary horticulture processor to ensure that premises and equipment are maintained, cleaned and if necessary sanitised; each to the extent needed to ensure that berries are not made unacceptable. The intent of these provisions is that premises and equipment, including transport vehicles, do not present a source of product contamination, damage or other adverse outcome.

Section 8: These provisions require a primary horticulture producer and a primary horticulture processor to ensure that persons engaged in; or supervising a person engaged in, relevant activities listed for berries have skills and knowledge in both food safety and food hygiene commensurate with their work. The purpose of this provision is to ensure those people do not make the product unacceptable through contamination or other adverse outcomes.

Section 9: These provisions require a primary horticulture producer and a primary horticulture processor to take all reasonable measures to ensure that personnel and visitors exercise personal hygiene and health practices that do not make berries unacceptable. The intent is that personnel and visitors do not present a source of product contamination or other adverse product outcome from illness or poor hygiene practices.

Section 10: These provisions prohibit a primary horticulture producer or a primary horticulture processor from selling or supplying berries for human consumption if they ought reasonably know, or ought reasonably suspect, that the relevant food is unacceptable. This requirement is intended to prevent the introduction or transfer of unacceptable berries through the fresh food supply chain.

Explanatory Statement

Approved draft Standard 4.2.8 – Primary Production and Processing requirements for Horticulture (Leafy Vegetables)

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 2 of Part 3 of the FSANZ Act specifies that the Authority may prepare a proposal for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering a proposal for the development or variation of food regulatory measures.

The Authority prepared Proposal P1052 – Primary Production and Processing requirements for Horticulture (berries, leafy vegetables and melons). The Authority considered the Proposal in accordance with Division 2 of Part 3 and has approved this draft Standard and a consequential variation.

2. Variation is a legislative instrument

The approved draft variation is a legislative instrument for the purposes of the *Legislation Act 2003* (see section 94 of the FSANZ Act) and is publicly available on the Federal Register of Legislation (www.legislation.gov.au).

This instrument is not subject to the disallowance or sunset provisions of the *Legislation Act 2003*. Subsections 44(1) and 54(1) of that Act provide that a legislative instrument is not disallowable or subject to sunset if the enabling legislation for the instrument (in this case, the FSANZ Act): (a) facilitates the establishment or operation of an intergovernmental scheme involving the Commonwealth and one or more States; and (b) authorises the instrument to be made for the purposes of the scheme. Regulation 11 of the *Legislation (Exemptions and other Matters) Regulation 2015* also exempts from sunset legislative instruments a primary purpose of which is to give effect to an international obligation of Australia.

The FSANZ Act gives effect to an intergovernmental agreement (the Food Regulation Agreement) and facilitates the establishment or operation of an intergovernmental scheme (national uniform food regulation). That Act also gives effect to Australia's obligations under an international agreement between Australia and New Zealand. For these purposes, the Act establishes the Authority to develop food standards for consideration and endorsement by the Food Ministers Meeting (FMM). The FMM is established under the Food Regulation Agreement and the international agreement between Australia and New Zealand, and consists of New Zealand, Commonwealth and State/Territory members. If endorsed by the FMM, the food standards on gazettal and registration are incorporated into and become part of Commonwealth, State and Territory and New Zealand food laws. These standards or instruments are then administered, applied and enforced by these jurisdictions' regulators as part of those food laws.

3. Purpose

The Authority has approved draft Standard 4.2.8 to minimise food safety risks associated with the primary production and processing of fresh leafy vegetables in Australia.

Leafy vegetables contaminated by pathogenic microorganisms present an unacceptable health risk to consumers. In recent years, outbreaks of foodborne illness have been associated with the consumption of leafy vegetables both in Australia and overseas.

The food regulatory measures in Standard 4.2.8, along with existing measures in the Code, address the public health and safety problem identified with leafy vegetables in the most cost-effective manner.

4. Documents incorporated by reference

The approved draft Standard does not incorporate any documents by reference.

5. Consultation

In accordance with the procedure in Division 2 of Part 3 of the FSANZ Act, the Authority's consideration of Proposal P1052 included two rounds of public comment following an assessment, targeted communication with key stakeholders, and the preparation of three draft standards and associated assessment summaries.

The first call for submissions was held between February and March 2020. Targeted consultation was undertaken in December 2020–January 2021. The second call for submissions was held between November 2021 and February 2022.

A Standards Development Advisory Group was established with representatives from the industry sector and State, Territory and federal government agencies to provide ongoing advice to FSANZ throughout the standard development process. A Horticulture Implementation Working Group comprised of State, Territory and federal government regulators was established by the Implementation Sub-committee for Food Regulation to work with FSANZ and ensure a nationally consistent approach to implementation of the standards.

A decision Regulation Impact Statement (DRIS) was prepared by the Authority and has been approved by The Office of Best Practice Regulation (Reference - OBPR22-01822).

6. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the *Legislation Act 2003*.

7. Approved Draft Standard

General: The approved draft Standard is introduced by two notes providing information about the place of the Standard within the Code and the application or otherwise of the Standard in New Zealand. The first note in the Standard explains that the instrument is a standard under the FSANZ Act, and that the Standard and the other standards together make up the Code. The second note in the Standard explains that the relevant draft Standard applies only in Australia.

Section 1: This provision establishes the name of the relevant Standard:

- the *Australia New Zealand Food Standards Code – Standard 4.2.8 - Primary Production and Processing Standard for Leafy Vegetables*.

The note to section 1 in the draft Standard explains that the Standard will commence on the date that is 30 months following the date of gazettal, being the date specified in accordance with section 92 of the FSANZ Act.

Section 2: This provision sets out the definitions for key words and phrases used in the standard, or signposts to where those definitions are provided in other standards in the Code.

Leafy vegetables means vegetables of a leafy nature where the leaf is consumed raw; and includes baby leaves, lettuce, and leafy herbs; and does not include seed sprouts. The definition is inclusive in that baby leaves, lettuce and leafy herbs are intended as examples of leafy vegetables, rather than constituting an exhaustive list. The intent is to include any vegetables and herbs (except seed sprouts) with one or more leaves when the leaves are consumed fresh and raw. 'Leafy vegetables' does not include seed sprouts. Seed sprouts are covered by Standard 4.2.6.

Growing site means any site used to grow leafy vegetables; and includes an open, partially enclosed or enclosed planting area. The definition clarifies that the Standard applies to open fields as well as other cropping arrangements in fully or partially enclosed structures, such as hydroponic set ups.

Harvest means all activities related to the collection and removal of leafy vegetables from a growing site; and includes picking, cutting, field packing (including packaging for retail sale), and transport from the growing site to the next step in the supply chain.

Premises and equipment means equipment, infrastructure, structures and vehicles that a) are used by a primary horticulture producer or by a primary horticulture processor; and b) have direct or indirect contact with leafy vegetables. Examples of 'indirect contact' include pipes used to carry irrigation water, and equipment that may be placed on a food contact surface.

Primary horticulture producer means a business, enterprise or activity that is involved in the growing and / or harvesting of leafy vegetables.

Primary horticulture processor means a business, enterprise or activity that is involved in one or more of the following activities in relation to leafy vegetables, that have been harvested: washing, trimming, sorting, sanitising, storing, combining products, packing, and transport between primary processing premises. Primary processing is intended to include minimal post-harvest processing activities and does not include further processing or manufacturing activities such as freezing, drying, cooking, canning or blending leafy vegetables with other ingredients. Transport other than transport from primary processing facilities is not included. Chapter 3 would already apply to these further processing and transport activities.

Relevant activity means, in relation to a primary horticulture producer, the growing and/or harvesting of leafy vegetables. In relation to a primary horticulture processor, relevant activities mean the following activities with harvested leafy vegetables: washing, trimming, sorting, sanitising, storing, combining products, packing, and transport between primary processing premises. The definition is provided to clarify which activities pertain to certain requirements in the Standard. Primary processing relevant activities are intended to include minimal post-harvest processing activities and not to include further processing or manufacturing activities such as freezing,

drying, cooking, canning or blending leafy vegetables with other ingredients. Chapter 3 would already apply to these further processing activities. Transport other than transport from primary processing facilities is not included in the definition. Chapter 3 would already apply to these transport activities.

Notes: Notes 1 and 2 in section 2 signpost relevant definitions contained in other parts of the Code. Note 1 refers readers to the definitions of *general food safety management requirements* and *inputs* in clause 1 of Standard 4.1.1. Note 2 refers readers to clause 3 of Standard 4.1.1, which sets out when a food will be unacceptable for the purposes of Chapter 4 Standards, which would include this draft Standard.

Section 3: This provision deals with the application of the draft Standard.

Subsection (1) provides that the draft Standard applies only to primary production and primary processing in Australia. The Standard does not apply to activities that are not captured by the definition of 'primary horticulture producer' and of 'primary horticulture processor'.

Subsection (2) provides that the Standard does not apply to retail sale activities of leafy vegetables. Chapter 3 of the Code already applies to retail activities.

Subsection (3) provides that the Standard does not apply to manufacturing activities of harvested leafy vegetables, which include but are not limited to cooking, freezing, drying, preserving, blending or juicing of harvested leafy vegetables or the addition of other foods to harvested leafy vegetables. Chapter 3 of the Code already applies to manufacturing activities.

Section 4: The provision in the draft Standard requires a primary horticulture producer and a primary horticulture processor of leafy vegetables to comply with the general food safety management requirements in Standard 4.1.1. Clauses 4 and 5 of Standard 4.1.1 set out the general food safety management requirements; and requirements specifically related to a food safety management statement (FSMS). The primary horticulture producer and primary horticulture processor need to (among other things) prepare a FSMS setting out how the requirements in Chapter 4 of the Code are being complied with. In accordance with clause 5 of Standard 4.1.1, this statement must be approved or endorsed or recognised by the relevant authority.

Section 5: This provision requires a primary horticulture producer and a primary horticulture processor to have a system in place that identifies from whom leafy vegetables were received and to whom they were supplied. The intent is that the system would enable the business to trace the produce one step back and one step forward, as a minimum. The required information will enable a rapid response and removal of unsafe produce if a food safety issue arises and/or a product recall is required.

Section 6: This provision requires a producer and a primary processor of leafy vegetables to take all reasonable measures to ensure that specified inputs do not make leafy vegetables unacceptable. The specified inputs are seeds, seedlings, soil, soil amendments (including manure, human biosolids, compost, and plant bio-waste), fertiliser, and water. 'Water' is intended to include recycled water, but is not intended to include falling rain.

Section 7: These provisions require a primary horticulture producer of leafy vegetables to ensure that a growing site is located, designed, constructed, maintained and operated such that leafy vegetables are not made unacceptable. These provisions also require ongoing management of growing sites by primary producers to ensure leafy vegetables do not become unacceptable during growing and harvest activities.

Section 8: These provisions require a primary horticulture producer and a primary horticulture processor to take appropriate remedial action to ensure that leafy vegetables adversely affected by weather conditions (e.g. a flood, hail storm or dust storm) are not unacceptable. The intent is that any unacceptable leafy vegetables do not enter the fresh produce supply chain. Examples of appropriate remedial action are product disposal, treatment of product to thoroughly remove adversely affected areas (e.g. through trimming, cleaning, sanitisation), or diversion of product to another supply chain where adequate treatment (e.g. retorting) will ensure the safety of the product.

Section 9: These provisions deal with premises and equipment. Subsection (1) of each provision requires a primary horticulture producer and a primary horticulture processor to take all reasonable measures to ensure that premises and equipment are designed, constructed, maintained and operated in a way that allows for effective cleaning and sanitisation of the premises and equipment; and does not make leafy vegetables unacceptable. Subsection (2) of each provision requires a primary horticulture producer and a primary horticulture processor to ensure that premises and equipment are maintained, cleaned and if necessary sanitised; each to the extent needed to ensure that leafy vegetables are not made unacceptable. The intent of these provisions is that premises and equipment, including transport vehicles, do not present a source of product contamination, damage or other adverse outcome.

Section 10: These provisions require a primary horticulture producer and a primary horticulture processor to keep harvested leafy vegetables at a temperature that would not make the produce unacceptable. The intent of these provisions is that harvested product is cooled, if necessary, and kept cool during post-harvest handling, transport and storage to prevent or minimise growth of any pathogenic microorganisms that may be present on harvested leafy vegetables. Primary producers and primary processors must consider the location and timing of relevant activities (for example, the time taken to harvest product and transport it to a primary processing facility), to ensure the harvested product does not remain at temperatures for a time that would enable microbial growth to levels that would make the product unacceptable.

Section 11: These provisions require a primary horticulture processor to take all reasonable measures to ensure that visible extraneous material (for example, surface dirt) is removed from harvested leafy vegetables, and that any wash or sanitisation step used does not make leafy vegetables unacceptable. The intent for washing is that where a wash step is used, the washing cleans the produce and does not introduce contamination (for example through use of excessively dirty water) or make the produce otherwise unacceptable. The intent for sanitisation is that when a sanitisation process is used, the process reduces microorganisms on the surface of leafy vegetables to safe levels and does not make the product unsafe or otherwise unacceptable; for example, through use of inadequate sanitiser concentration. Under Standard 4.1.1, only approved chemicals can be used to treat fresh leafy vegetables.

Section 12: These provisions require a primary horticulture producer and a primary horticulture processor to take all reasonable measures to minimise the presence of animals, vermin and pests at growing sites and in premises and equipment, to ensure that leafy vegetables are not made unacceptable. The intent of this requirement is that growing areas, premises and equipment are designed, constructed and maintained in such a way to prevent and minimise entry and harbourage of domestic or wild animals, vermin and pests to an extent that would cause leafy vegetables to become unacceptable.

Section 13: These provisions require a primary horticulture producer and a primary horticulture processor to ensure that persons engaged in; or supervising a person engaged

in, relevant activities listed for leafy vegetables have skills and knowledge in both food safety and food hygiene commensurate with their work. The purpose of this provision is to ensure those people do not make the product unacceptable through contamination or other adverse outcomes.

Section 14: These provisions require a primary horticulture producer and a primary horticulture processor to take all reasonable measures to ensure that personnel and visitors exercise personal hygiene and health practices that do not make leafy vegetables unacceptable. The intent is that personnel and visitors do not present a source of product contamination or other adverse product outcome from illness or poor hygiene practices.

Section 15: These provisions prohibit a primary horticulture producer or a primary horticulture processor from selling or supplying leafy vegetables for human consumption if they ought reasonably know, or ought reasonably suspect, that the relevant food is unacceptable. This requirement is intended to prevent the introduction or transfer of unacceptable leafy vegetables through the fresh food supply chain.

Explanatory Statement

Approved draft Standard 4.2.9 – Primary Production and Processing requirements for Horticulture (Melons)

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 2 of Part 3 of the FSANZ Act specifies that the Authority may prepare a proposal for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering a proposal for the development or variation of food regulatory measures.

The Authority prepared Proposal P1052 – Primary Production and Processing requirements for Horticulture (berries, leafy vegetables and melons). The Authority considered the Proposal in accordance with Division 2 of Part 3 and has approved this draft Standard and a consequential variation.

2. Variation is a legislative instrument

The approved draft variation is a legislative instrument for the purposes of the *Legislation Act 2003* (see section 94 of the FSANZ Act) and is publicly available on the Federal Register of Legislation (www.legislation.gov.au).

This instrument is not subject to the disallowance or sunset provisions of the *Legislation Act 2003*. Subsections 44(1) and 54(1) of that Act provide that a legislative instrument is not disallowable or subject to sunset if the enabling legislation for the instrument (in this case, the FSANZ Act): (a) facilitates the establishment or operation of an intergovernmental scheme involving the Commonwealth and one or more States; and (b) authorises the instrument to be made for the purposes of the scheme. Regulation 11 of the *Legislation (Exemptions and other Matters) Regulation 2015* also exempts from sunset legislative instruments a primary purpose of which is to give effect to an international obligation of Australia.

The FSANZ Act gives effect to an intergovernmental agreement (the Food Regulation Agreement) and facilitates the establishment or operation of an intergovernmental scheme (national uniform food regulation). That Act also gives effect to Australia's obligations under an international agreement between Australia and New Zealand. For these purposes, the Act establishes the Authority to develop food standards for consideration and endorsement by the Food Ministers Meeting (FMM). The FMM is established under the Food Regulation Agreement and the international agreement between Australia and New Zealand, and consists of New Zealand, Commonwealth and State/Territory members. If endorsed by the FMM, the food standards on gazettal and registration are incorporated into and become part of Commonwealth, State and Territory and New Zealand food laws. These standards or instruments are then administered, applied and enforced by these jurisdictions' regulators as part of those food laws.

3. Purpose

The Authority has approved draft Standard 4.2.9 to minimise food safety risks associated with the primary production and processing of fresh melons in Australia.

Melons contaminated by pathogenic microorganisms present an unacceptable health risk to consumers. In recent years, outbreaks of foodborne illness have been associated with the consumption of melons both in Australia and overseas.

The food regulatory measures in Standard 4.2.9, along with existing measures in the Code, address the public health and safety problem identified with melons in the most cost-effective manner.

4. Documents incorporated by reference

The approved draft Standard does not incorporate any documents by reference.

5. Consultation

In accordance with the procedure in Division 2 of Part 3 of the FSANZ Act, the Authority's consideration of Proposal P1052 included two rounds of public comment following an assessment, targeted communication with key stakeholders, and the preparation of three draft standards and associated assessment summaries.

The first call for submissions was held between February and March 2020. Targeted consultation was undertaken in December 2020–January 2021. The second call for submissions was held between November 2021 and February 2022.

A Standards Development Advisory Group was established with representatives from the industry sector and State, Territory and federal government agencies to provide ongoing advice to FSANZ throughout the standard development process. A Horticulture Implementation Working Group comprised of State, Territory and federal government regulators was established by the Implementation Sub-committee for Food Regulation to work with FSANZ and ensure a nationally consistent approach to implementation of the standards.

A decision Regulation Impact Statement (DRIS) was prepared by the Authority and has been approved by The Office of Best Practice Regulation (Reference - OBPR22-01822).

6. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the *Legislation Act 2003*.

7. Approved draft Standard

General: The approved draft Standard is introduced by two notes providing information about the place of the Standards within the Code and the application or otherwise of the relevant Standard in New Zealand. The first note in the Standard explains that the instrument is a standard under the FSANZ Act, and that the Standard and the other standards together make up the Code. The second note in the Standard explains that the approved draft Standard applies only in Australia.

Section 1 This provision establishes the name of the Standard:

- the *Australia New Zealand Food Standards Code – Standard 4.2.9 – Primary Production and Processing Standard for Melons*.

The note to section 1 in the draft Standard explains that the Standard will commence on the date that is 30 months following the date of gazettal, being the date specified in accordance with section 92 of the FSANZ Act.

Section 2: This provision sets out the definitions for key words and phrases used in the standards, or signposts to where those definitions are provided in other standards in the Code.

Melons means fresh melons and includes watermelon, rockmelon, honeydew melon, and piel de sapo. The definition is inclusive in that the specific products listed in it are intended as examples of melons, rather than constituting an exhaustive list.

Growing site means any site used to grow melons; and includes an open, partially enclosed or enclosed planting area. The definition clarifies that the Standard applies to open fields as well as other cropping arrangements in fully or partially enclosed structures, such as hydroponic set ups.

Harvest means all activities related to the collection and removal of melons from a growing site; and includes picking, cutting, field packing (including packaging for retail sale), and transport from the growing site to the next step in the supply chain.

Premises and equipment means equipment, infrastructure, structures and vehicles that a) are used by a primary horticulture producer or by a primary horticulture processor; and b) have direct or indirect contact with melons. Examples of 'indirect contact' include pipes used to carry irrigation water, and equipment that may be placed on a food contact surface.

Primary horticulture producer means a business, enterprise or activity that is involved in the growing and / or harvesting of melons.

Primary horticulture processor means a business, enterprise or activity that is involved in one or more of the following activities in relation to melons, that have been harvested: washing, trimming, sorting, sanitising, storing, combining products, packing, and transport between primary processing premises. Primary processing is intended to include minimal post-harvest processing activities and does not include further processing or manufacturing activities such as freezing, drying, cooking, canning or blending melons with other ingredients. Transport other than transport from primary processing facilities is not included. Chapter 3 would already apply to these further processing and transport activities.

Relevant activity means, in relation to a primary horticulture producer, the growing and/or harvesting of melons. In relation to a primary horticulture processor, relevant activities mean the following activities with harvested melons: washing, trimming, sorting, sanitising, storing, combining products, packing, and transport between primary processing premises. The definition is provided to clarify which activities pertain to certain requirements in the Standard. Primary processing relevant activities are intended to include minimal post-harvest processing activities and not to include further processing or manufacturing activities such as freezing, drying, cooking, canning or blending melons with other ingredients. Chapter 3 would already apply to these further processing activities. Transport other than transport from primary processing facilities is not included in the definition. Chapter 3 would already apply to these transport activities.

Notes: Notes 1 and 2 in section 2 signpost relevant definitions contained in other parts of the Code. Note 1 refers readers to the definitions of *general food safety management requirements* and *inputs* in clause 1 of Standard 4.1.1. Note 2 refers readers to clause 3 of Standard 4.1.1, which sets out when a food will be unacceptable for the purposes of Chapter 4 Standards, which would include this draft Standard.

Section 3: This provision deals with the application of the draft Standard.

Subsection (1) provides that the draft Standard applies only to primary production and primary processing in Australia. The Standard does not apply to activities that are not captured by the definition of 'primary horticulture producer' and of 'primary horticulture processor'.

Subsection (2) provides that the Standard does not apply to retail sale activities of melons. Chapter 3 of the Code already applies to retail activities.

Subsection (3) provides that the Standard does not apply to manufacturing activities of harvested melons, which include but are not limited to cooking, freezing, drying, preserving, blending or juicing of harvested melons or the addition of other foods to harvested melons. Chapter 3 of the Code already applies to manufacturing activities.

Section 4: The provision in the draft Standard requires a primary horticulture producer and a primary horticulture processor of melons to comply with the general food safety management requirements in Standard 4.1.1. Clauses 4 and 5 of Standard 4.1.1 set out the general food safety management requirements; and requirements specifically related to a food safety management statement (FSMS). The primary horticulture producer and primary horticulture processor need to (among other things) prepare a FSMS setting out how the requirements in Chapter 4 of the Code are being complied with. In accordance with clause 5 of Standard 4.1.1, this statement must be approved or endorsed or recognised by the relevant authority.

Section 5: This provision requires a primary horticulture producer and a primary horticulture processor to have a system in place that identifies from whom melons were received and to whom they were supplied. The intent is that the system would enable the business to trace the produce one step back and one step forward, as a minimum. The required information will enable a rapid response and removal of unsafe produce if a food safety issue arises and/or a product recall is required.

Section 6: This provision requires a primary producer and a primary processor of melons to take all reasonable measures to ensure inputs do not make melons unacceptable. The specified inputs are soil, soil amendments (including manure, human biosolids, compost, and plant bio-waste), fertilisers and water. 'Water' is intended to include recycled water, but is not intended to include falling rain.

Section 7: These provisions require a primary horticulture producer of melons to ensure that a growing site is located, designed, constructed, maintained and operated such that melons are not made unacceptable. These provisions also require ongoing management of growing sites by primary producers to ensure melons do not become unacceptable during growing and harvest activities.

Section 8: These provisions require a primary horticulture producer and a primary horticulture processor to take appropriate remedial action to ensure that melons adversely affected by weather conditions (e.g. a flood, hail storm or dust storm) are not unacceptable. The intent is that any unacceptable melons do not enter the fresh produce supply chain. Examples of appropriate remedial action are product disposal, treatment of product to

thoroughly remove adversely affected areas (e.g. through trimming, cleaning, sanitisation), or diversion of product to another supply chain where adequate treatment (e.g. retorting) will ensure the safety of the product.

Section 9: These provisions deal with premises and equipment. Subsection (1) of each provision requires a primary horticulture producer and a primary horticulture processor to take all reasonable measures to ensure that premises and equipment are designed, constructed, maintained and operated in a way that allows for effective cleaning and sanitisation of the premises and equipment; and does not make melons unacceptable. Subsection (2) of each provision requires a primary horticulture producer and a primary horticulture processor to ensure that premises and equipment are maintained, cleaned and if necessary sanitised; each to the extent needed to ensure that melons are not made unacceptable. The intent of these provisions is that premises and equipment, including transport vehicles, do not present a source of product contamination, damage or other adverse outcome.

Section 10: These provisions require a primary horticulture producer and a primary horticulture processor to keep harvested melons at a temperature that would not make the produce unacceptable. The intent of these provisions is that harvested product is cooled, if necessary, and kept cool during post-harvest handling, transport and storage to prevent or minimise growth of any pathogenic microorganisms that may be present on harvested melons. Primary producers and primary processors must consider the location and timing of relevant activities (for example, the time taken to harvest product and transport it to a primary processing facility), to ensure the harvested product does not remain at temperatures for a time that would enable microbial growth to levels that would make the product unacceptable.

Section 11: These provisions require a primary horticulture processor to take all reasonable measures to ensure that visible extraneous material (for example, surface dirt) is removed from harvested melons, and that any wash or sanitisation step used does not make melons unacceptable. The intent for washing is that where a wash step is used, the washing cleans the produce and does not introduce contamination (for example through use of excessively dirty water) or make the produce otherwise unacceptable. The intent for sanitisation is that when a sanitisation process is used, the process reduces microorganisms on the surface of melons to safe levels and does not make the product unsafe or otherwise unacceptable; for example, through use of inadequate sanitiser concentration. Under Standard 4.1.1, only approved chemicals can be used to treat fresh melons.

Section 12: These provisions require a primary horticulture producer and a primary horticulture processor to take all reasonable measures to minimise the presence of animals, vermin and pests at growing sites and in premises and equipment, to ensure that melons are not made unacceptable. The intent of this requirement is that growing areas, premises and equipment are designed, constructed and maintained in such a way to prevent and minimise entry and harbourage of domestic or wild animals, vermin and pests to an extent that would cause melons to become unacceptable.

Section 13: These provisions require a primary horticulture producer and a primary horticulture processor to ensure that persons engaged in; or supervising a person engaged in, relevant activities listed for melons have skills and knowledge in both food safety and food hygiene commensurate with their work. The purpose of this provision is to ensure those people do not make the product unacceptable through contamination or other adverse outcomes.

Section 14: These provisions require a primary horticulture producer and a primary horticulture processor to take all reasonable measures to ensure that personnel and visitors

exercise personal hygiene and health practices that do not make melons unacceptable. The intent is that personnel and visitors do not present a source of product contamination or other adverse product outcome from illness or poor hygiene practices.

Section 15: These provisions prohibit a primary horticulture producer or a primary horticulture processor from selling or supplying melons for human consumption if they ought reasonably know, or ought reasonably suspect, that the relevant food is unacceptable. This requirement is intended to prevent the introduction or transfer of unacceptable melons through the fresh food supply chain.

Food Standards (Proposal P1052 – Primary Production and Processing requirements for Horticulture (Berries, Leafy Vegetables and Melons) – Consequential Amendments) Variation

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 2 of Part 3 of the FSANZ Act specifies that the Authority may prepare a proposal for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering a proposal for the development or variation of food regulatory measures.

The Authority prepared Proposal P1052 to consider mandating the use of three primary production and processing requirements for horticulture (berries, leafy vegetables and melons). The Authority considered the Proposal in accordance with Division 2 of Part 3 and has prepared three draft standards and a draft consequential variation to Standard 1.1.1.

2. Purpose

The Authority has prepared a draft variation called *Food Standards (Proposal P1052 – Primary Production and Processing requirements for Horticulture (Berries, Leafy Vegetables and Melons) – Consequential Amendments) Variation* to make a consequential amendment to Standard 1.1.1 to account for the commencement of Standards 4.2.7, 4.2.8 and 4.2.9.

3. Documents incorporated by reference

The draft consequential variation does not incorporate any documents by reference.

4. Consultation

In accordance with the procedure in Division 2 of Part 3 of the FSANZ Act, the Authority's consideration of Proposal P1052 included two rounds of public consultation following an assessment, targeted communication with key stakeholders, and the preparation of three draft standards and associated assessment summaries.

The first call for submissions was held between February and March 2020. Targeted consultation was undertaken in December 2020–January 2021. The second call for submissions was held between November 2021 and February 2022.

A Standards Development Advisory Group was established with representatives from the industry sector and State, Territory and federal government agencies to provide ongoing advice to FSANZ throughout the standard development process. A Horticulture Implementation Working Group comprised of State, Territory and federal government regulators was established by the Implementation Sub-committee for Food Regulation to work with FSANZ and ensure a nationally consistent approach to implementation of the standards.

A Decision Regulation Impact Statement (DRIS) was prepared by the Authority and has been approved by The Office of Best Practice Regulation (Reference - OBPR22-01822).

5. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the FSANZ Act.

6. Variation

Clause 1 provides that the name of the variation is *Food Standards (Proposal P1052 – Primary Production and Processing requirements for Horticulture (Berries, Leafy Vegetables and Melons – Consequential Amendments) Variation*.

Clause 2 provides that the Code is amended by the Schedule to the variation.

Clause 3 provides that the variation will commence immediately after draft Standards 4.2.7, 4.2.8 and 4.2.9 take effect.

Item [1] of the draft Variation amends subsection 1.1.1—2(2) by omitting the reference to ‘Standard 4.2.6 Production and Processing Standard for Seed Sprouts’ in the list of standards in that subsection and replacing that reference with references to:

“Standard 4.2.6 Production and Processing Standard for Seed Sprouts
Standard 4.2.7 Primary Production and Processing Standard for Berries
Standard 4.2.8 Primary Production and Processing Standard for Leafy Vegetables
Standard 4.2.9 Primary Production and Processing Standard for Melons”

Subsection 1.1.1—2(2) lists all the standards of the Code arranged into Chapters, Parts and a set of Schedules. The list does not currently contain references to the new standards.

The effect of this amendment is that the new draft standards are listed in subsection 1.1.1—2(2), under Chapter 4 (Primary production standards), in numerical order according to the number of the relevant Standard.

Clause 4 of the *Food Standards (Proposal P1052 – Primary Production and Processing Requirements for Horticulture (Berries, Leafy Vegetables and Melons) – Consequential Amendments) Variation* (the draft Variation) states that the draft Variation commences after the new draft Standards commence.

Attachment C – Draft variations to the *Australia New Zealand Food Standards Code* provided in 2nd call for submissions

Draft variation to the *Australia New Zealand Food Standards Code* – Berries



Standard 4.2.7 – Primary production and processing standard for Berries

The Board of Food Standards Australia New Zealand gives notice of the making of this Standard under section 92 of the *Food Standards Australia New Zealand Act 1991*. The Standard commences on a date 18 months after the date of gazettal.

Dated [To be completed by the Delegate]

[Name of Delegate]

Delegate of the Board of Food Standards Australia New Zealand

Note:

This Standard will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX. This means that this date is the gazettal date for the purposes of the above notice.

Standard 4.2.7 Primary production and processing standard for Berries

Note 1 This instrument is a standard under the *Food Standards Australia New Zealand Act 1991* (Cth). The standards together make up the *Australia New Zealand Food Standards Code*. See also section 1.1.1—3.

Note 2 This Standard applies in Australia only.

Division 1 Preliminary

4.2.7—1 Name

This Standard is *Australia New Zealand Food Standards Code – Standard 4.2.7 – Primary production and processing standard for Berries*.

Note Commencement:
This Standard commences on a date 18 months after the date of gazettal, being the date specified as the commencement date in notices in the *Gazette* and the *New Zealand Gazette* under section 92 of the *Food Standards Australia New Zealand Act 1991* (Cth). See also section 93 of that Act.

4.2.7—2 Definitions

In this Standard:

berries means fresh berries; and includes strawberries, blueberries, and raspberries.

growing site means any site used to grow berries; and includes an open, partially enclosed or enclosed planting area.

harvest means all activities related to the collection and removal of berries from a growing site; and includes picking, cutting, field packing (including packaging for retail sale), and transport from the growing site to the next step in the supply chain.

premises and equipment means equipment, infrastructure, structures and vehicles that:

- (a) are used by a primary horticulture producer or by a primary horticulture processor; and
- (b) have direct or indirect contact with berries.

primary horticulture producer means a business, enterprise or activity that involves the growing and/or harvesting of berries.

primary horticulture processor means a business, enterprise or activity that involves one or more of the following activities in relation to berries that have been harvested:

- (a) washing;
- (b) trimming;
- (c) chopping;
- (d) sorting;
- (e) sanitising;
- (f) combining products;
- (g) packing; and
- (h) transport between primary processing premises.

relevant activity means:

- (a) in relation to a primary horticulture producer, the growing and/or harvesting of berries; and

- (b) in relation to a primary horticulture processor, any the following:
 - (i) washing harvested berries;
 - (ii) trimming harvested berries;
 - (iii) chopping harvested berries;
 - (iv) sorting harvested berries;
 - (v) sanitising harvested berries;
 - (vi) combining harvested berries;
 - (vii) packing harvested berries; and
 - (viii) transporting harvested berries between primary processing premises.

Note 1 In this Code (see section 1.1.2—2(3) of Standard 1.1.2)

relevant authority means an authority responsible for the enforcement of the relevant application Act

Note 2 In this Chapter (see clause 1 of Standard 4.1.1):

inputs includes any feed, litter, water (including recycled water), chemicals or other substances used in, or in connection with, the primary production or processing activity.

Note 3 Clause 3 of Standard 4.1.1 sets out when a food will be unacceptable for the purposes of this Standard.

4.2.7—3 Application

- (1) This Standard applies to primary horticulture producers and to primary horticulture processors in Australia.
- (2) This Standard does not apply to the retail sale of berries.

4.2.7—4 Notification

- (1) A primary horticulture producer and a primary horticulture processor must provide the specified information to the relevant authority before engaging in a relevant activity.
- (2) In this section, **specified information** means the following information:
 - (a) the contact details of the primary horticulture producer or the primary horticulture processor, including the name of their business and the name and business address of the proprietor of their business;
 - (b) a description of the activities the primary horticulture producer or the primary horticulture processor will undertake in relation to berries; and
 - (c) the location or locations of each activity referred to in paragraph (b) that is within the jurisdiction of the relevant authority.
- (3) A primary horticulture producer and a primary horticulture processor must notify the relevant authority of any proposed change to specified information provided to a relevant authority in accordance with this section before that change occurs.

4.2.7—5 Traceability

A primary horticulture producer and a primary horticulture processor must have in place a system that can identify:

- (d) from whom berries were received; and
- (e) to whom berries were supplied.

4.2.7—6 Inputs - water

A primary horticulture producer and a primary horticulture processor must take all reasonable measures to ensure that water inputs do not make the berries unacceptable.

4.2.7—7 Premises and equipment

- (1) A primary horticulture producer and a primary horticulture processor must take all reasonable measures to ensure that premises and equipment are designed, constructed, maintained and operated in a way that:
 - (a) allows for effective cleaning and sanitisation of the premises and equipment; and
 - (b) does not make berries unacceptable.
- (2) A primary horticulture producer and a primary horticulture processor must ensure that premises and equipment are kept clean, sanitised and in good repair to the extent required to ensure that berries are not made unacceptable.

4.2.7—8 Skills and knowledge

A primary horticulture producer and a primary horticulture processor must ensure that persons who engage in a relevant activity, or who supervise a person who engages in a relevant activity, have:

- (e) knowledge of food safety and food hygiene matters; and
- (f) skills in food safety and food hygiene matters

commensurate with their work.

4.2.7—9 Health and hygiene of personnel and visitors

A primary horticulture producer and a primary horticulture processor must take all reasonable measures to ensure that personnel and visitors exercise personal hygiene and health practices that do not make berries unacceptable.

4.2.7—10 Sale or supply of unacceptable berries

A primary horticulture producer and a primary horticulture processor must not sell or supply berries for human consumption if they ought reasonably know, or ought reasonably suspect, that the berries are unacceptable.

Draft variation to the *Australia New Zealand Food Standards Code – Leafy Vegetables*



Standard 4.2.8 – Primary production and processing standard for Leafy Vegetables

The Board of Food Standards Australia New Zealand gives notice of the making of this Standard under section 92 of the *Food Standards Australia New Zealand Act 1991*. The Standard commences on a date 18 months after the date of gazettal.

Dated [To be completed by the Delegate]

[Name of Delegate]

Delegate of the Board of Food Standards Australia New Zealand

Note:

This Standard will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX. This means that this date is the gazettal date for the purposes of the above notice.

Standard 4.2.8 Primary production and processing standard for Leafy Vegetables

Note 1 This instrument is a standard under the *Food Standards Australia New Zealand Act 1991* (Cth). The standards together make up the *Australia New Zealand Food Standards Code*. See also section 1.1.1—3.

Note 2 This Standard applies in Australia only.

Division 1 Preliminary

4.2.8—1 Name

This Standard is *Australia New Zealand Food Standards Code – Standard 4.2.8 – Primary production and processing standard for Leafy Vegetables*.

Note Commencement:
This Standard commences on a date 18 months after the date of gazettal, being the date specified as the commencement date in notices in the *Gazette* and the *New Zealand Gazette* under section 92 of the *Food Standards Australia New Zealand Act 1991* (Cth). See also section 93 of that Act.

4.2.8—2 Definitions

In this Standard:

leafy vegetables means fresh leafy vegetables; and includes baby leaves, lettuce, and leafy herbs.

growing site means any site used to grow leafy vegetables; and includes an open, partially enclosed or enclosed planting area.

harvest means all activities related to the collection and removal of leafy vegetables from a growing site; and includes picking, cutting, field packing (including packaging for retail sale), and transport from the growing site to the next step in the supply chain.

premises and equipment means equipment, infrastructure, structures and vehicles that:

- (a) are used by a primary horticulture producer or by a primary horticulture processor; and
- (b) have direct or indirect contact with leafy vegetables.

primary horticulture producer means a business, enterprise or activity that involves the growing and/or harvesting of leafy vegetables.

primary horticulture processor means a business, enterprise or activity that includes one or more of the following activities in relation to leafy vegetables that have been harvested:

- (a) washing;
- (b) trimming;
- (c) chopping;
- (d) sorting;
- (e) sanitising;
- (f) combining products;
- (g) packing; and
- (h) transport between primary processing premises.

relevant activity means:

- (a) in relation to a primary horticulture producer, the growing and/or harvesting of leafy vegetables; and

- (b) in relation to a primary horticulture processor, any the following:
 - (i) washing harvested leafy vegetables;
 - (ii) trimming harvested leafy vegetables;
 - (iii) chopping harvested leafy vegetables;
 - (iv) sorting harvested leafy vegetables;
 - (v) sanitising harvested leafy vegetables;
 - (vi) combining harvested leafy vegetables;
 - (vii) packing harvested leafy vegetables; and
 - (viii) transporting harvested leafy vegetables between primary processing premises.

Note 1 In this Chapter (see clause 1 of Standard 4.1.1):

general food safety management requirements means the requirements in Division 2 of Standard 4.1.1.

inputs includes any feed, litter, water (including recycled water), chemicals or other substances used in, or in connection with, the primary production or processing activity.

Note 2 Clause 3 of Standard 4.1.1 sets out when a food will be unacceptable for the purposes of this Standard.

4.2.8—3 Application

- (1) This Standard applies to primary horticulture producers and to primary horticulture processors in Australia.
- (2) This Standard does not apply to the retail sale of leafy vegetables.

4.2.8—4 General food safety management requirements

A primary horticulture producer and a primary horticulture processor must comply with the general food safety management requirements.

4.2.8—5 Traceability

A primary horticulture producer and a primary horticulture processor must have in place a system that can identify:

- (a) from whom leafy vegetables were received; and
- (b) to whom leafy vegetables were supplied.

4.2.8—6 Inputs – seed, seedling, soil, fertiliser and water

A primary horticulture producer and a primary horticulture processor must take all reasonable measures to ensure that any of the following inputs do not make leafy vegetables unacceptable:

- (g) seeds;
- (h) seedlings;
- (i) soil;
- (j) soil amendments (including manure, human biosolids, compost, and plant bio-waste);
- (k) fertiliser; and
- (l) water.

4.2.8—7 Growing sites

A primary horticulture producer must take all reasonable measures to ensure that a growing site is located, designed, constructed, maintained and operated such that leafy vegetables are not made unacceptable.

4.2.9—8**Weather events**

A primary horticulture producer and a primary horticulture processor must take appropriate remedial action to ensure that leafy vegetables adversely affected by weather conditions are not unacceptable.

4.2.8—9**Premises and equipment**

- (1) A primary horticulture producer and a primary horticulture processor must take all reasonable measures to ensure that premises and equipment are designed, constructed, maintained and operated in a way that:
 - (a) allows for effective cleaning and sanitisation of the premises and equipment; and
 - (b) does not make leafy vegetables unacceptable.
- (2) A primary horticulture producer and a primary horticulture processor must ensure that premises and equipment are kept clean, sanitised and in good repair to the extent required to ensure that leafy vegetables are not made unacceptable.

4.2.8—10**Temperature of harvested leafy vegetables**

A primary horticulture producer and a primary horticulture processor must keep harvested leafy vegetables at a temperature that does not make the leafy vegetables unacceptable.

4.2.8—11**Washing and sanitisation of harvested leafy vegetables**

A primary horticulture processor must take all reasonable measures to ensure that:

- (a) visible extraneous material on harvested leafy vegetables is removed; and
- (b) any washing or sanitising of harvested leafy vegetables does not make the leafy vegetables unacceptable.

4.2.8—12**Animals and pests**

A primary horticulture producer and a primary horticulture processor must take all reasonable measures to minimise the presence of animals, vermin and pests in growing sites, and in premises and equipment, to ensure that leafy vegetables are not made unacceptable.

4.2.8—13**Skills and knowledge**

A primary horticulture producer and a primary horticulture processor must ensure that persons who engage in a relevant activity, or who supervise a person who engages in a relevant activity, have:

- (a) knowledge of food safety and food hygiene matters; and
- (b) skills in food safety and food hygiene matters

commensurate with their work.

4.2.8—14**Health and hygiene of personnel and visitors**

A primary horticulture producer and a primary horticulture processor must take all reasonable measures to ensure that personnel and visitors exercise personal hygiene and health practices that do not make leafy vegetables unacceptable.

4.2.8—15**Sale or supply of unacceptable leafy vegetables**

A primary horticulture producer and a primary horticulture processor must not sell or supply leafy vegetables for human consumption if they ought reasonably know, or ought reasonably suspect, that the leafy vegetables are unacceptable.

Draft variation to the *Australia New Zealand Food Standards Code – Melons*



Standard 4.2.9 – Primary production and processing standard for Melons

The Board of Food Standards Australia New Zealand gives notice of the making of this Standard under section 92 of the *Food Standards Australia New Zealand Act 1991*. The Standard commences on a date 18 months after the date of gazettal.

Dated [To be completed by the Delegate]

[Name of Delegate]

Delegate of the Board of Food Standards Australia New Zealand

Note:

This Standard will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX. This means that this date is the gazettal date for the purposes of the above notice.

Standard 4.2.9 Primary production and processing standard for Melons

Note 1 This instrument is a standard under the *Food Standards Australia New Zealand Act 1991* (Cth). The standards together make up the *Australia New Zealand Food Standards Code*. See also section 1.1.1—3.

Note 2 This Standard applies in Australia only.

Division 1 Preliminary

4.2.9—1 Name

This Standard is *Australia New Zealand Food Standards Code* – Standard 4.2.9 – Primary production and processing standard for Melons.

Note Commencement:
This Standard commences on a date 18 months after the date of gazettal, being the date specified as the commencement date in notices in the *Gazette* and the *New Zealand Gazette* under section 92 of the *Food Standards Australia New Zealand Act 1991* (Cth). See also section 93 of that Act.

4.2.9—2 Definitions

In this Standard:

melons means fresh melons; and includes watermelon, rock melon, honeydew melon, and piel de sapo.

growing site means any site used to grow melons; and includes an open, partially enclosed or enclosed planting area.

harvest means all activities related to the collection and removal of melons from a growing site; and includes picking, cutting, field packing (including packaging for retail sale), and transport from the growing site to the next step in the supply chain.

premises and equipment means equipment, infrastructure, structures and vehicles that:

- (a) are used by a primary horticulture producer and a primary horticulture processor; and
- (b) have direct or indirect contact with melons.

primary horticulture producer means a business, enterprise or activity that involves the growing and/or harvesting of melons.

primary horticulture processor means a business, enterprise or activity that involves one or more of the following activities in relation to melons that have been harvested:

- (a) washing;
- (b) trimming;
- (c) chopping;
- (d) sorting;
- (e) sanitising;
- (f) combining products;
- (g) packing; and
- (h) transport between primary processing premises.

relevant activity means:

- (a) in relation to a primary horticulture producer, the growing and/or harvesting of melons; and

- (b) in relation to a primary horticulture processor, any the following:
 - (i) washing harvested melons;
 - (ii) trimming harvested melons;
 - (iii) chopping harvested melons;
 - (iv) sorting harvested melons;
 - (v) sanitising harvested melons;
 - (vi) combining harvested melons;
 - (vii) packing harvested melons; and
 - (viii) transporting harvested melons between primary processing premises.

Note 1 In this Chapter (see clause 1 of Standard 4.1.1):

general food safety management requirements means the requirements in Division 2 of Standard 4.1.1.

inputs includes any feed, litter, water (including recycled water), chemicals or other substances used in, or in connection with, the primary production or processing activity.

Note 2 Clause 3 of Standard 4.1.1 sets out when a food will be unacceptable for the purposes of this Standard.

4.2.9—3 Application

- (1) This Standard applies to primary horticulture producers and to primary horticulture processors in Australia.
- (2) This Standard does not apply to the retail sale of melons.

4.2.9—4 General food safety management requirements

A primary horticulture producer and a primary horticulture processor must comply with the general food safety management requirements.

4.2.9—5 Traceability

A primary horticulture producer and a primary horticulture processor must have in place a system that can identify:

- (a) from whom melons were received; and
- (b) to whom melons were supplied.

4.2.9—6 Inputs – soil, fertiliser and water

A primary horticulture producer and a primary horticulture processor must take all reasonable measures to ensure that any of the following inputs do not make the melons unacceptable:

- (a) soil;
- (b) soil amendments (including manure, human biosolids, compost, and plant bio-waste);
- (c) fertiliser; and
- (d) water.

4.2.9—7 Growing sites

A primary horticulture producer must take all reasonable measures to ensure that a growing site is located, designed, constructed, maintained and operated such that melons are not made unacceptable.

4.2.9—8 Weather events

A primary horticulture producer and a primary horticulture processor must take appropriate remedial action to ensure that melons adversely affected by weather conditions are not unacceptable.

4.2.9—9 Premises and equipment

- (1) A primary horticulture producer and a primary horticulture processor must take all reasonable measures to ensure that premises and equipment are designed, constructed, maintained and operated in a way that:
 - (a) allows for effective cleaning and sanitisation of the premises and equipment; and
 - (b) does not make melons unacceptable.
- (2) A primary horticulture producer and a primary horticulture processor must ensure that premises and equipment are kept clean, sanitised and in good repair to the extent required to ensure that melons are not made unacceptable.

4.2.9—10 Temperature of harvested melons

A primary horticulture producer and a primary horticulture processor must keep harvested melons at a temperature that does not make the melons unacceptable.

4.2.9—11 Washing and sanitisation of harvested melons

A primary horticulture processor must take all reasonable measures to ensure that:

- (a) visible extraneous material on harvested melons is removed; and
- (b) any washing or sanitising of harvested melons does not make the melons unacceptable.

4.2.9—12 Animals and pests

A primary horticulture producer and a primary horticulture processor must take all reasonable measures to minimise the presence of animals, vermin and pests in growing sites, and in premises and equipment, to ensure that melons are not made unacceptable.

4.2.9—13 Skills and knowledge

A primary horticulture producer and a primary horticulture processor must ensure that persons who engage in a relevant activity, or who supervise a person who engages in a relevant activity, have:

- (g) knowledge of food safety and food hygiene matters; and
- (h) skills in food safety and food hygiene matters

commensurate with their work.

4.2.9—14 Health and hygiene of personnel and visitors

A primary horticulture producer and a primary horticulture processor must take all reasonable measures to ensure that personnel and visitors exercise personal hygiene and health practices that do not make melons unacceptable.

4.2.9—15 Sale or supply of unacceptable melons

A primary horticulture producer and a primary horticulture processor must not sell or supply melons for human consumption if they ought reasonably know, or ought reasonably suspect, that the melons are unacceptable.

Draft variation to the Code consequential to the proposed standards



Food Standards (Proposal P1052 – Primary Production and Processing Requirements for Horticulture (Berries, Leafy Vegetables and Melons) – Consequential Amendments) Variation

The Board of Food Standards Australia New Zealand gives notice of the making of this Variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The Variation commences on the date specified in clause 3 of this Variation.

Dated [To be completed by the Delegate]

[Name of Delegate]

Delegate of the Board of Food Standards Australia New Zealand

Note:

This Variation will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX. This means that this date is the gazettal date for the purposes of the above notice.

1 Name

This instrument is the *Food Standards (Proposal P1052 – Primary Production and Processing Requirements for Horticulture (Berries, Leafy Vegetables and Melons) – Consequential Amendments) Variation*.

2 Variation to Standards in the *Australia New Zealand Food Standards Code*

The Schedule varies a Standard in the *Australia New Zealand Food Standards Code*.

3 Commencement

The Variation commences immediately after all of the following Standards have commenced:

- (d) Standard 4.2.7;
- (e) Standard 4.2.8;
- (f) Standard 4.2.9.

SCHEDULE

Standard 1.1.1—Structure of the Code and general provisions

[2] Subsection 1.1.1—2(2)

Omit:

Standard 4.2.6 Production and Processing Standard for Seed Sprouts

Substitute:

Standard 4.2.6 Production and Processing Standard for Seed Sprouts

Standard 4.2.7 Primary Production and Processing Standard for Berries

Standard 4.2.8 Primary Production and Processing Standard for Leafy Vegetables

Standard 4.2.9 Primary Production and Processing Standard for Melons